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Cully

(10) **Patent No.: US 10,596,352 B2**
(45) **Date of Patent: *Mar. 24, 2020**

(54) **FENESTRATION DEVICES, SYSTEMS, AND METHODS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 451 days.

This patent is subject to a terminal disclaimer.

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(65) **Prior Publication Data**

US 2017/0216565 A1 Aug. 3, 2017

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(Continued)

(51) **Int. Cl.**
A61M 25/06 (2006.01)
A61B 1/00 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61M 25/0662*** (2013.01); ***A61B 1/00154*** (2013.01); ***A61B 17/3403*** (2013.01);
(Continued)

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CPC A61F 2/2466; A61F 2/013; A61B 17/1285; A61B 17/0469; A61B 2017/047; A61B 2017/0472
See application file for complete search history.

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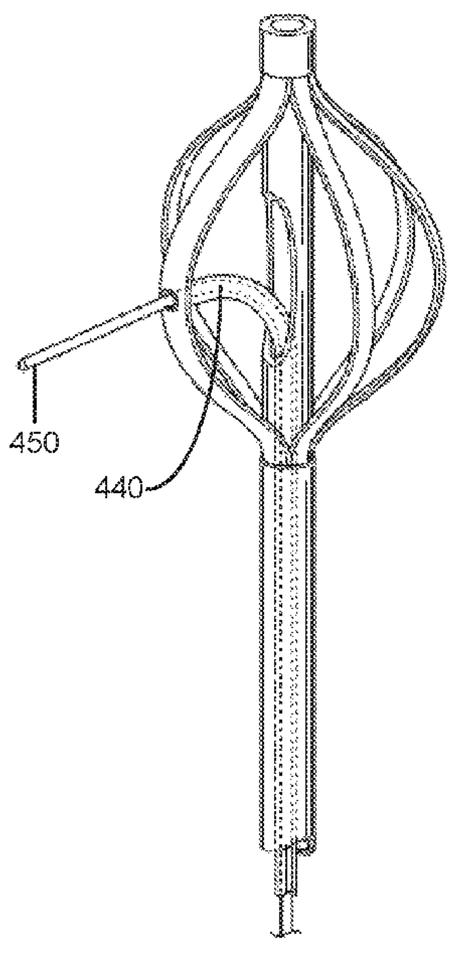
Primary Examiner — Alexander J Orkin

(57) **ABSTRACT**

The present disclosure provides methods and apparatuses for guiding an endovascular tool, such as a puncturing tool or an angioscope, in a radial direction, such as toward or through the sidewall of a vessel, stent, or stent graft, using elongate members and specialized catheters. The present disclosure provides methods and apparatuses for locating branch vessels from within a grafted main vessel while maintaining continuous blood flow to the branch vessel. Another aspect of the present disclosure involves a reverse cannulation system, particularly useful for stenting the abdominal aorta proximate the renal arteries and stenting the renal artery.

10 Claims, 11 Drawing Sheets



Related U.S. Application Data

(60) Provisional application No. 61/414,155, filed on Nov. 16, 2010.

(51) **Int. Cl.**

A61F 2/07	(2013.01)
A61F 2/958	(2013.01)
A61B 17/34	(2006.01)
A61M 25/01	(2006.01)
A61B 18/14	(2006.01)
A61F 2/06	(2013.01)
A61M 25/10	(2013.01)
A61F 2/89	(2013.01)

(52) **U.S. Cl.**

CPC ***A61F 2/07*** (2013.01); ***A61F 2/958*** (2013.01); ***A61M 25/0108*** (2013.01); *A61B 1/00082* (2013.01); *A61B 1/00085* (2013.01); *A61B 18/1492* (2013.01); *A61F 2/89* (2013.01); *A61F 2002/061* (2013.01); *A61F 2250/0007* (2013.01); *A61M 2025/1045* (2013.01)

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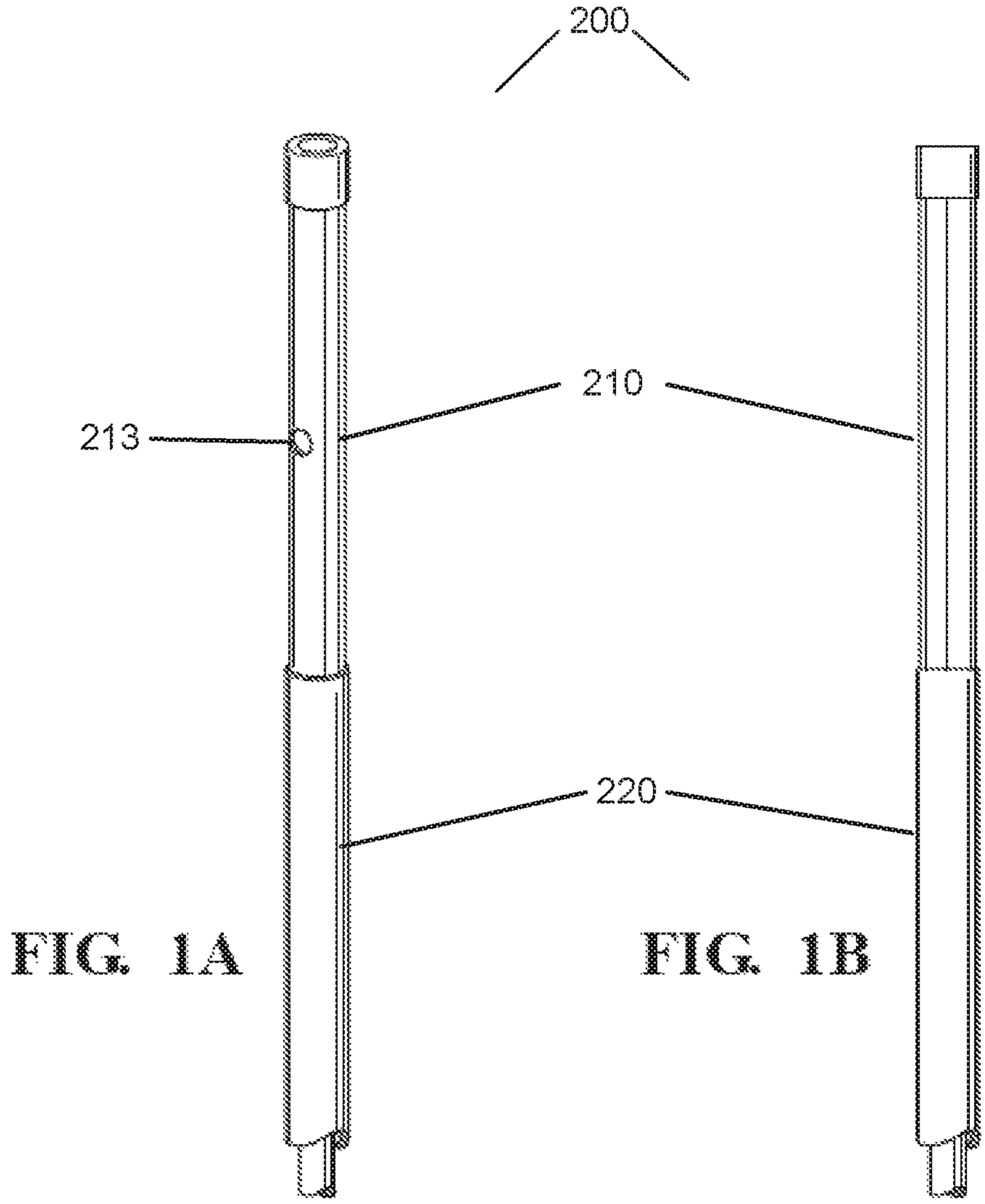

FIG. 1A

FIG. 1B

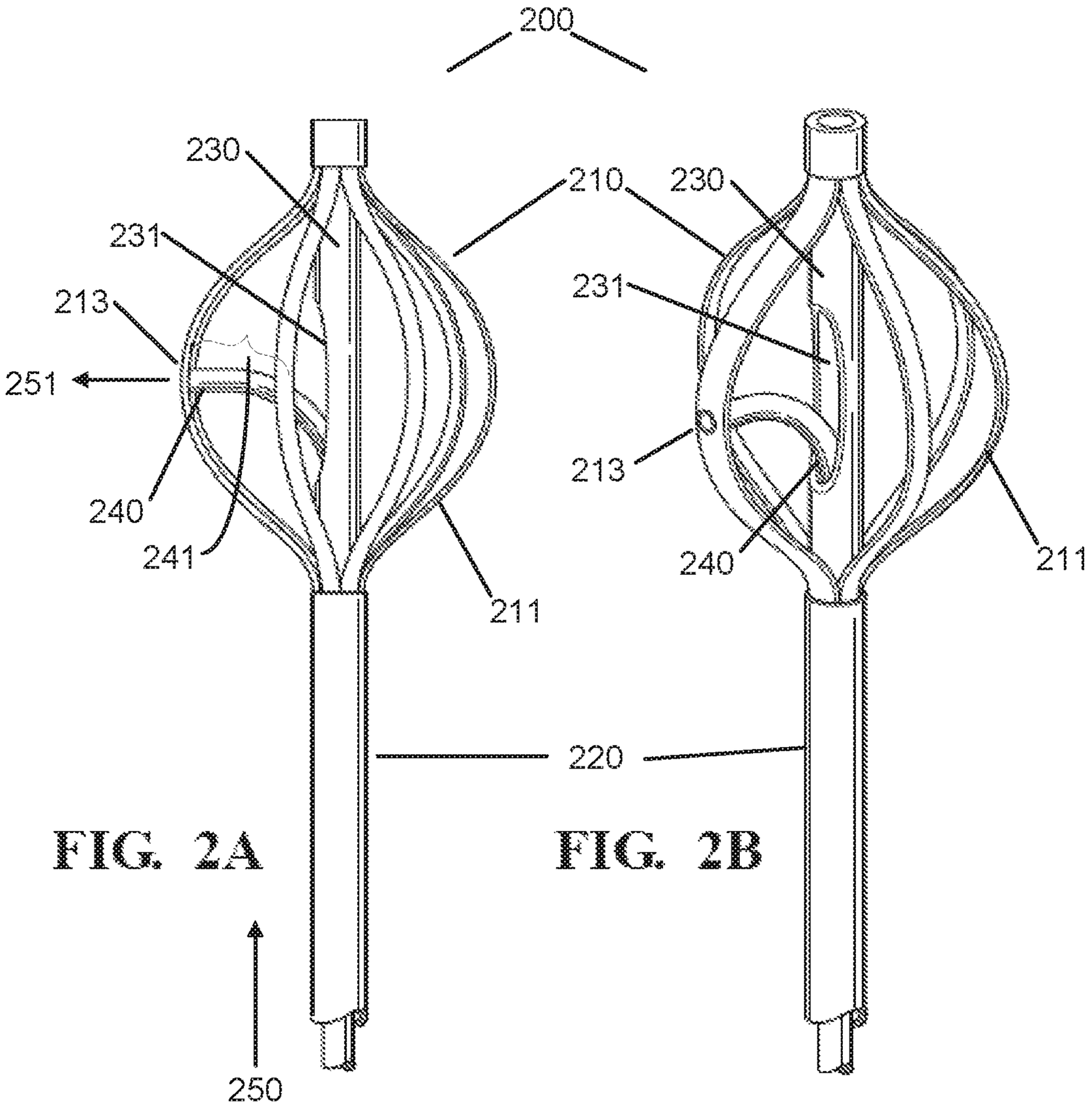
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FIG. 2A

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FIG. 2B

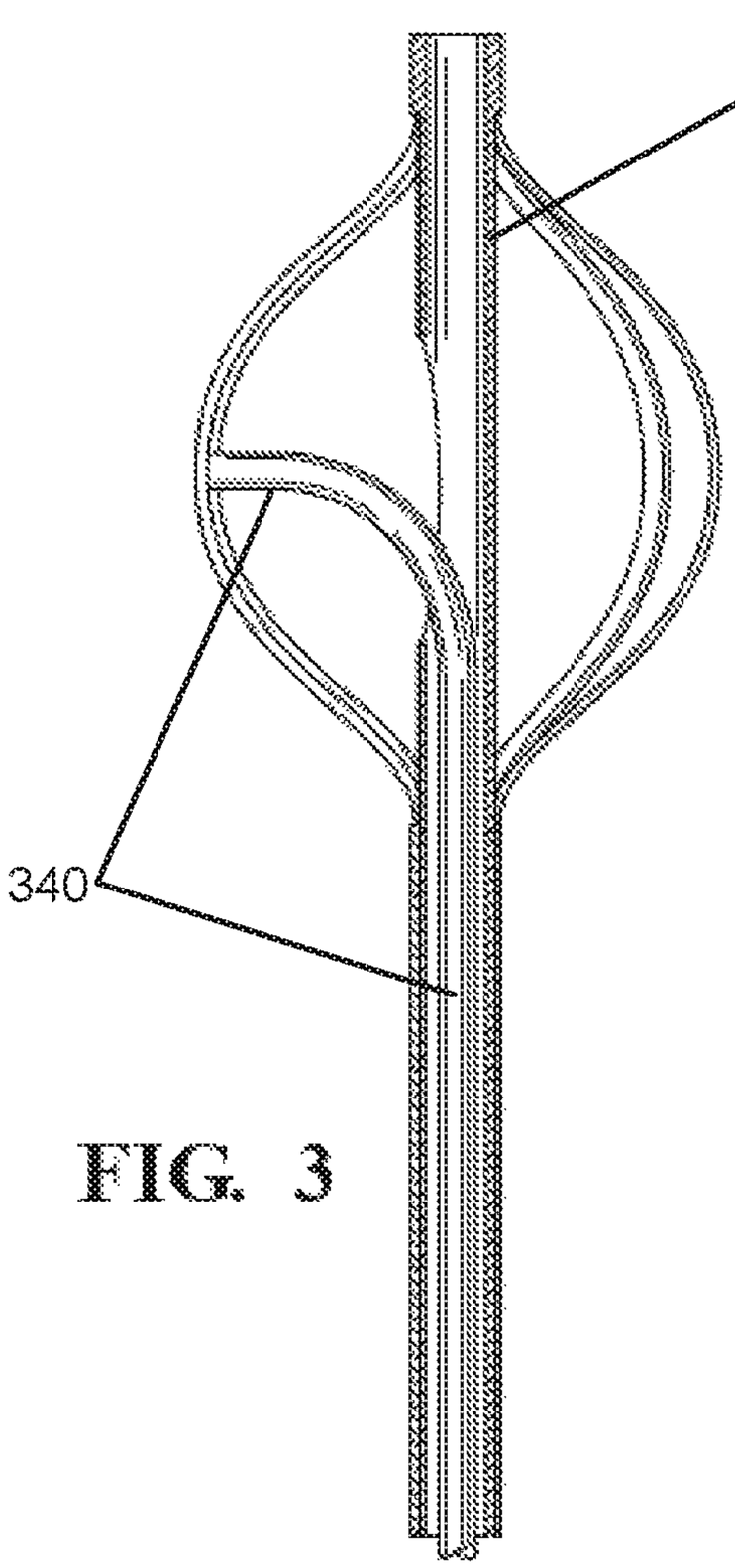

FIG. 3

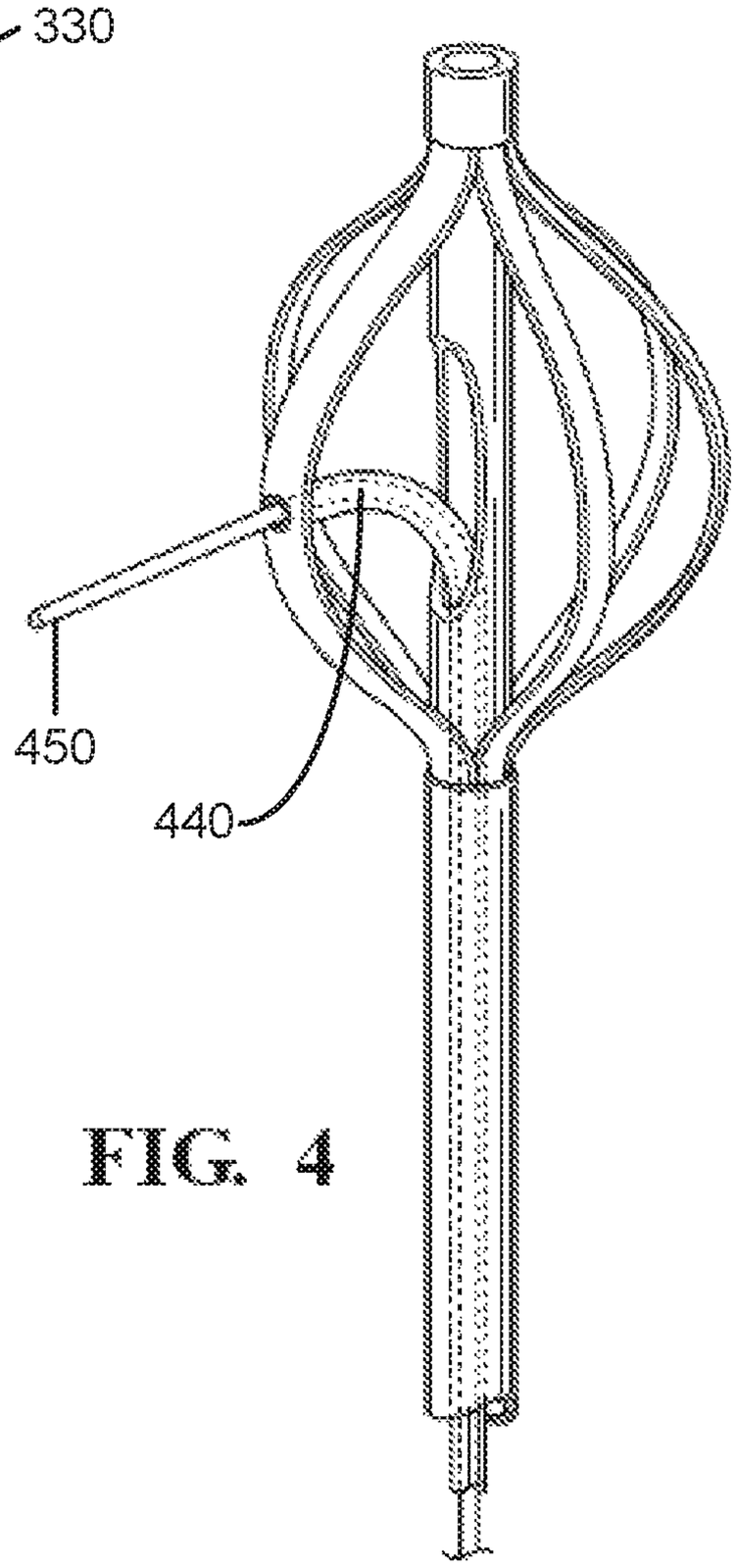

FIG. 4

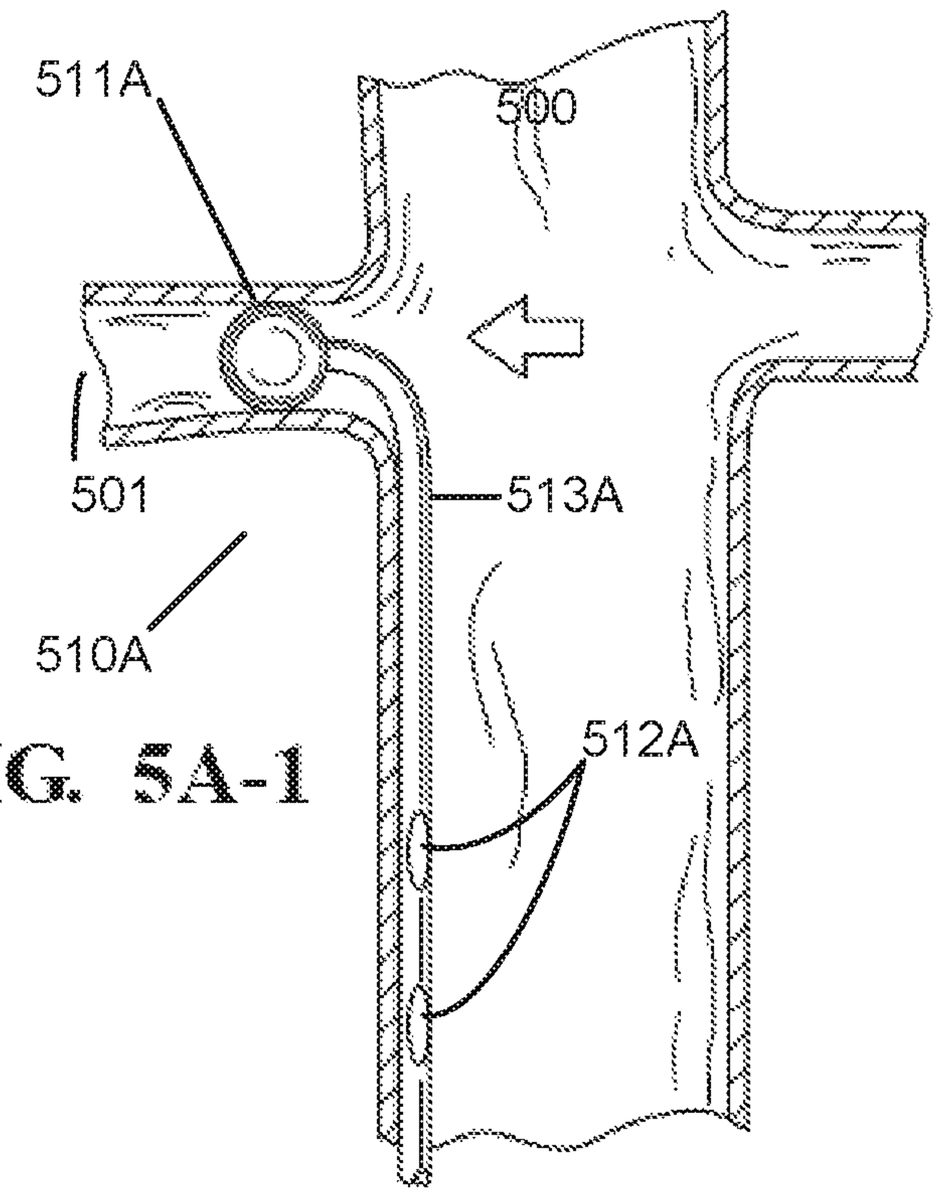

FIG. 5A-1

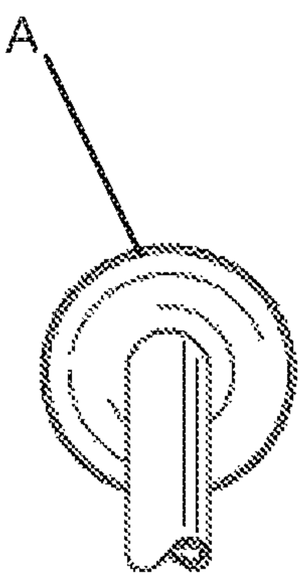

FIG. 5A-2

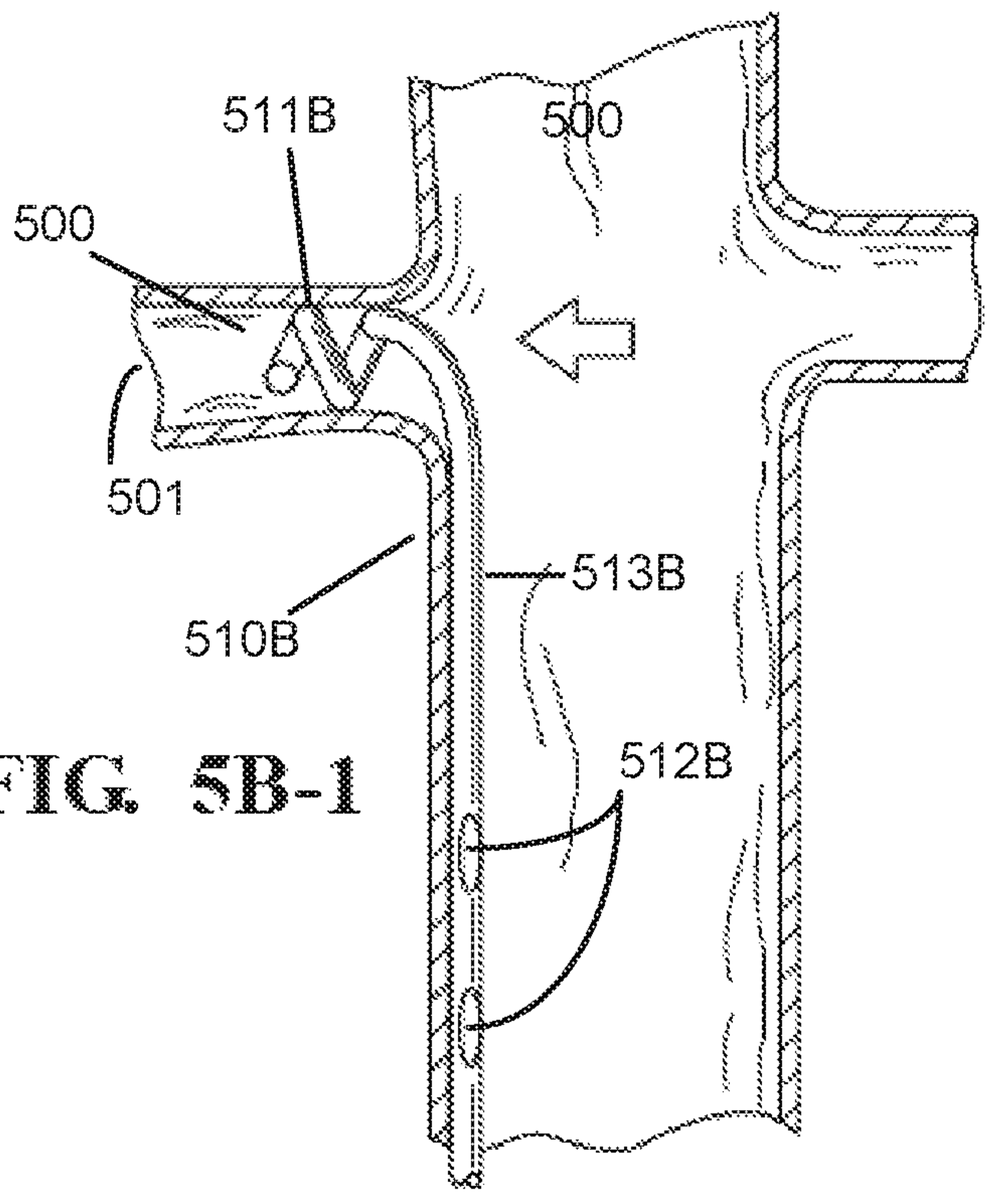

FIG. 5B-1

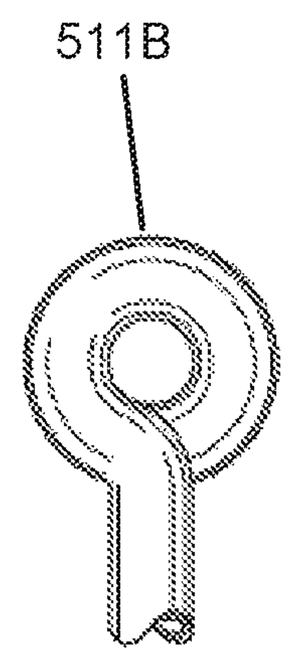

FIG. 5B-2

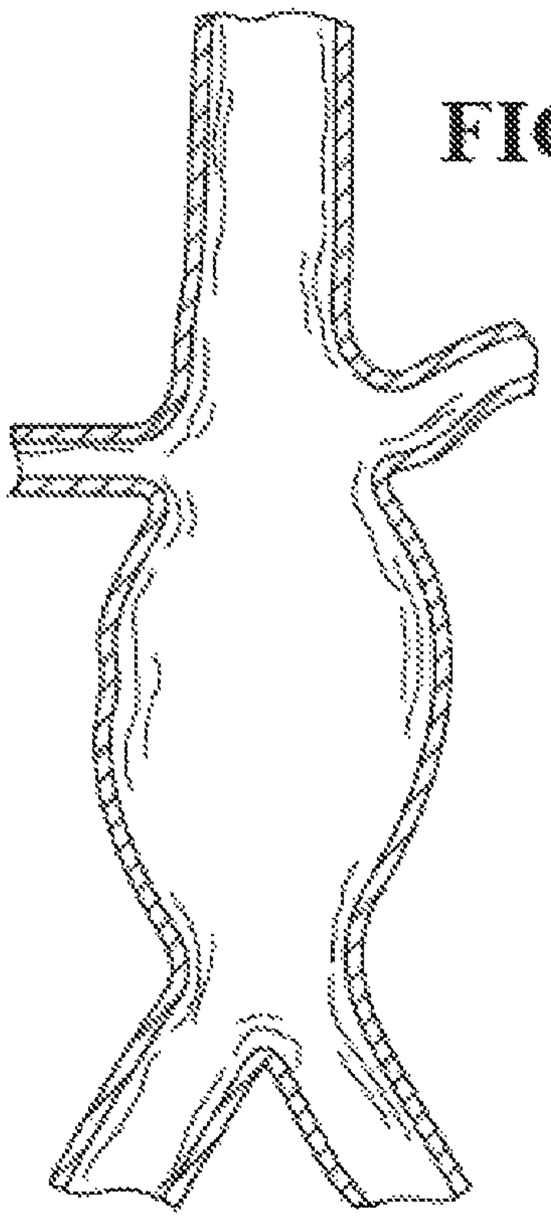

FIG. 6A-1

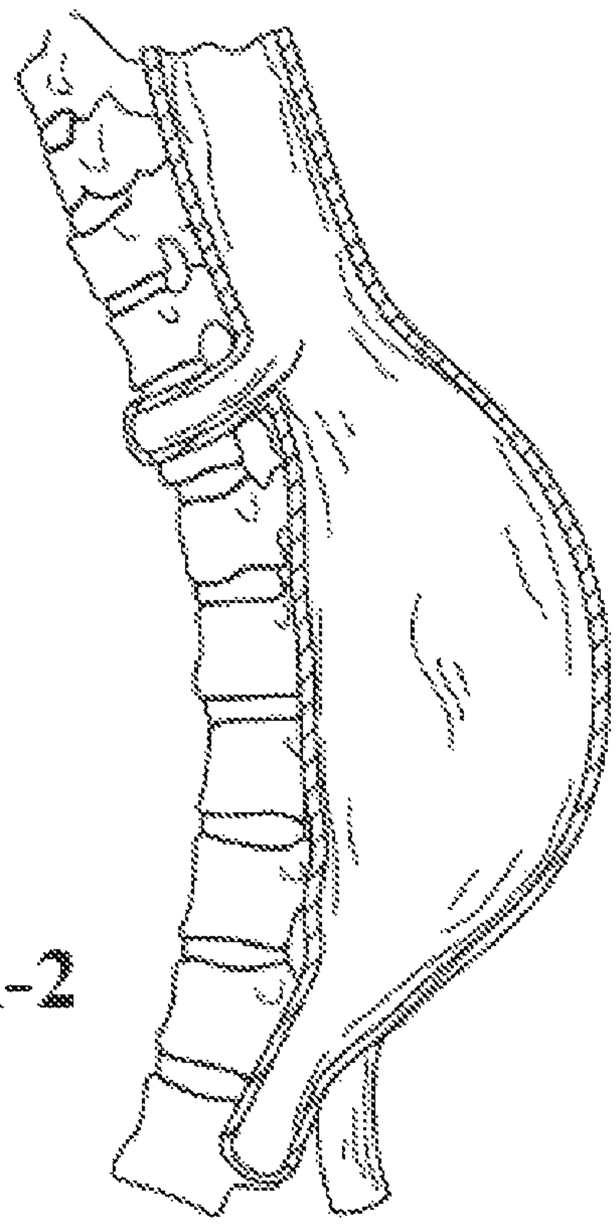

FIG. 6A-2

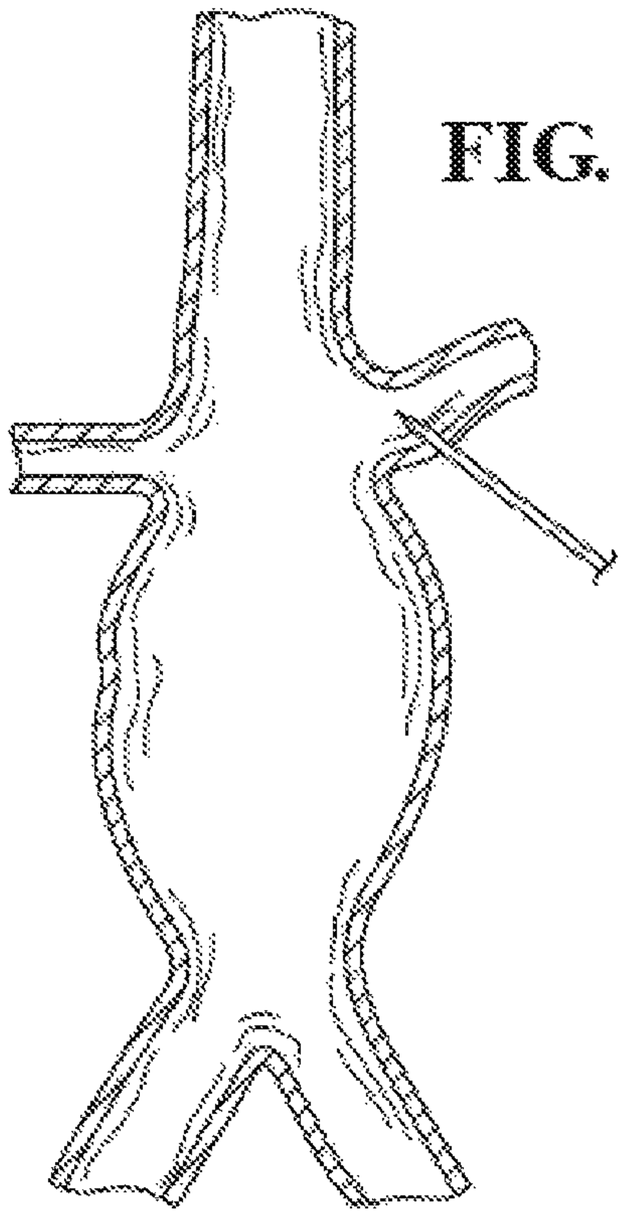

FIG. 6B-1

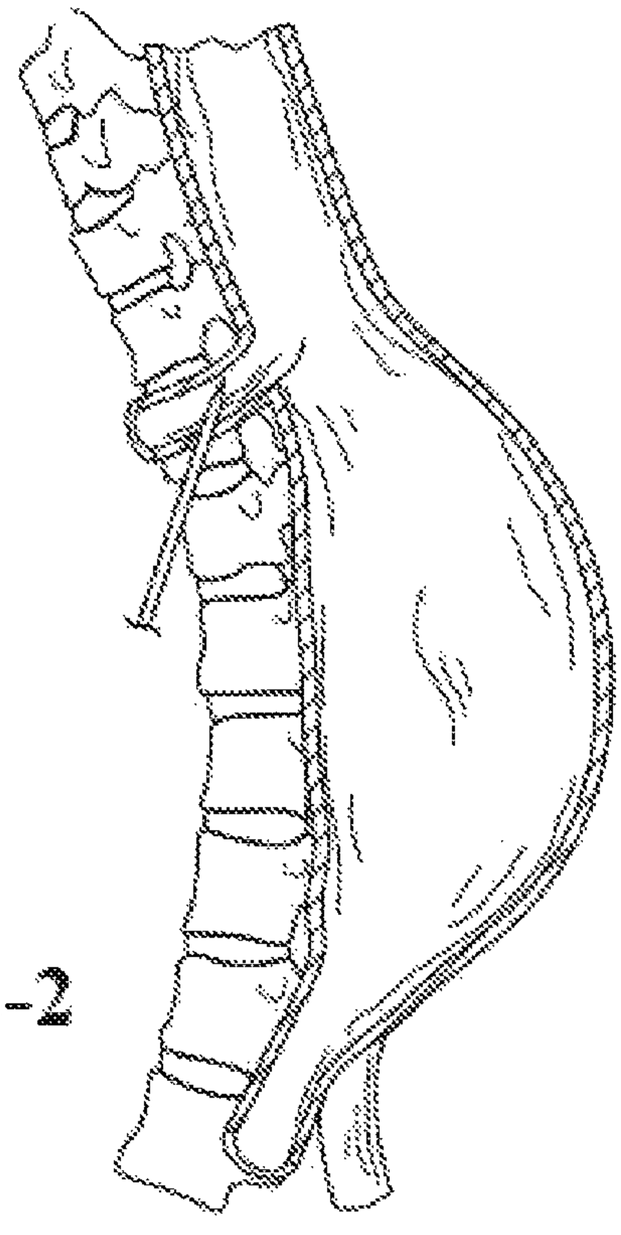

FIG. 6B-2

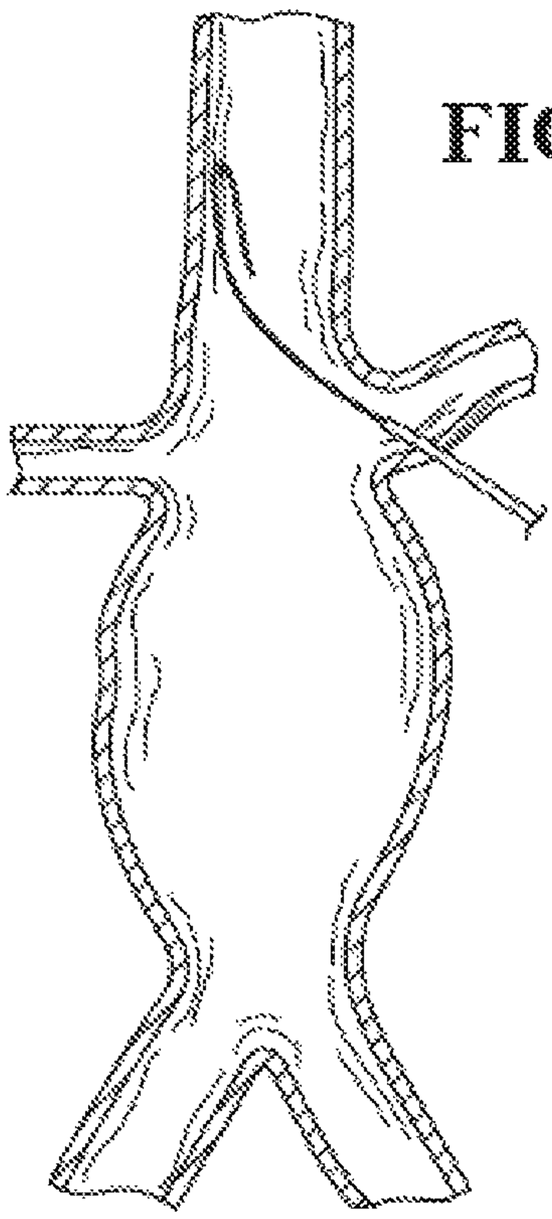

FIG. 6C-1

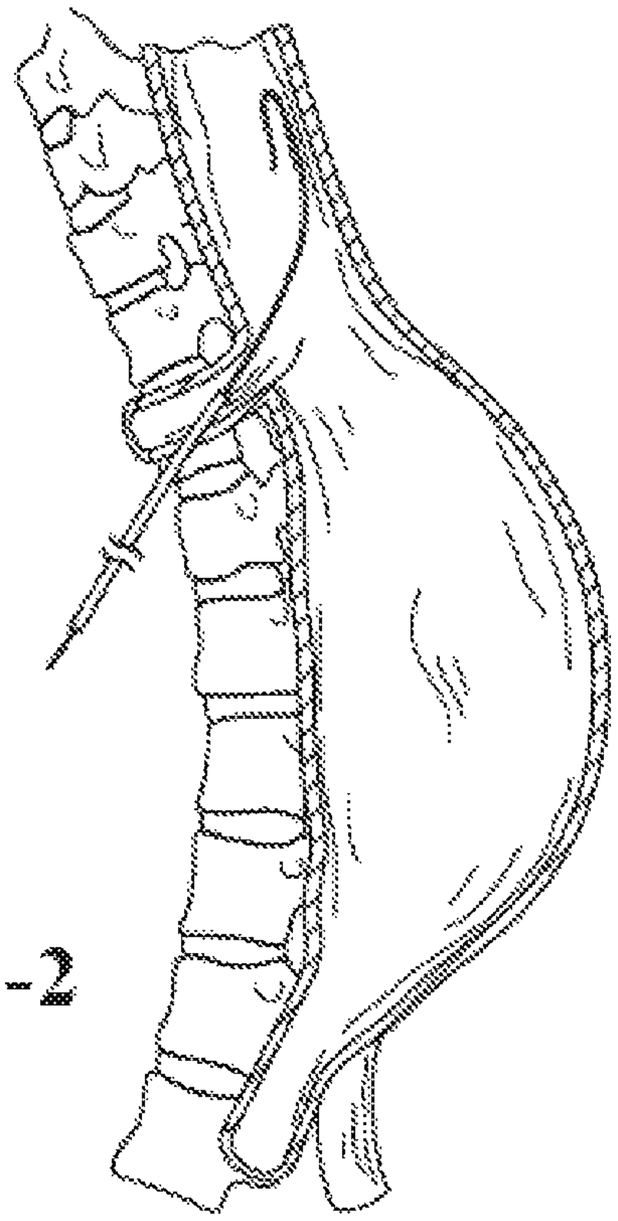

FIG. 6C-2

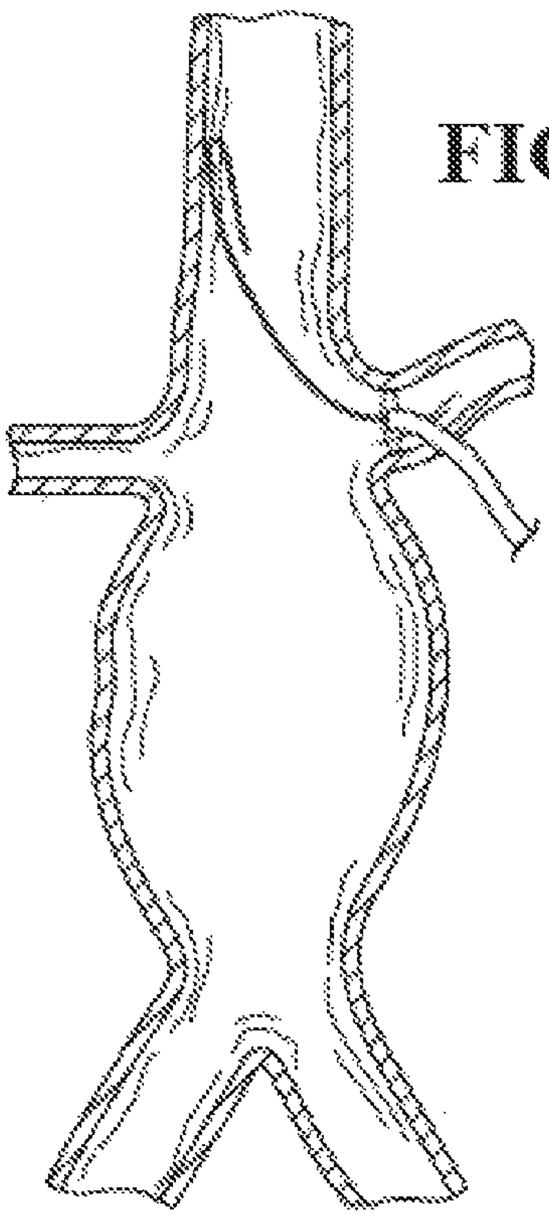

FIG. 6D-1

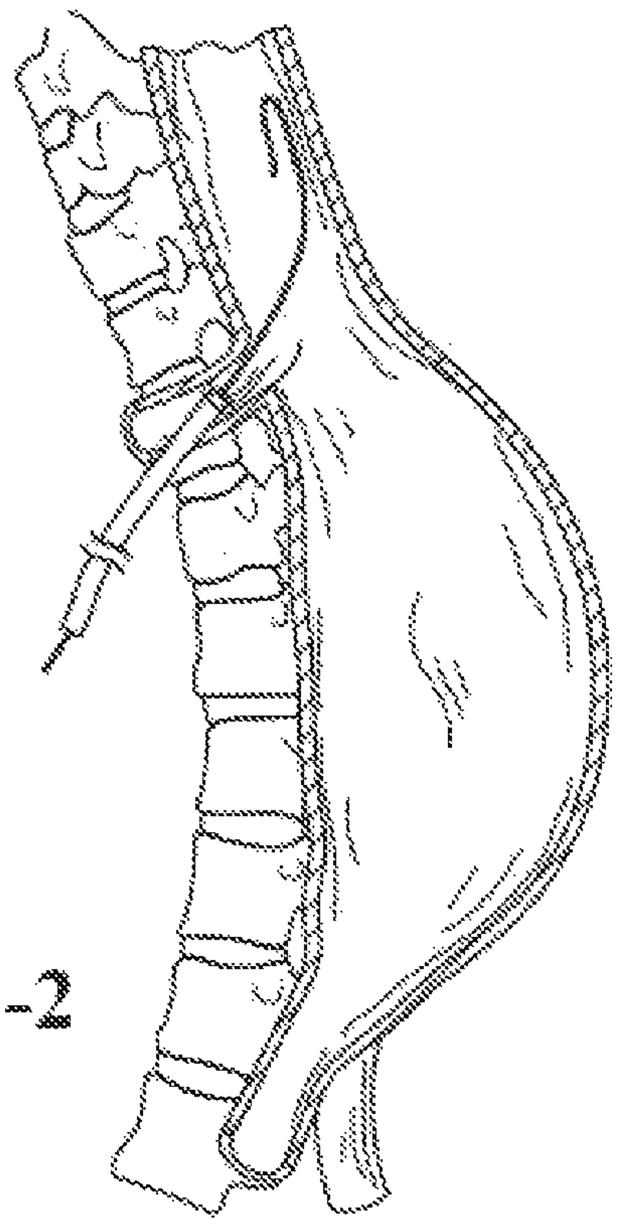

FIG. 6D-2

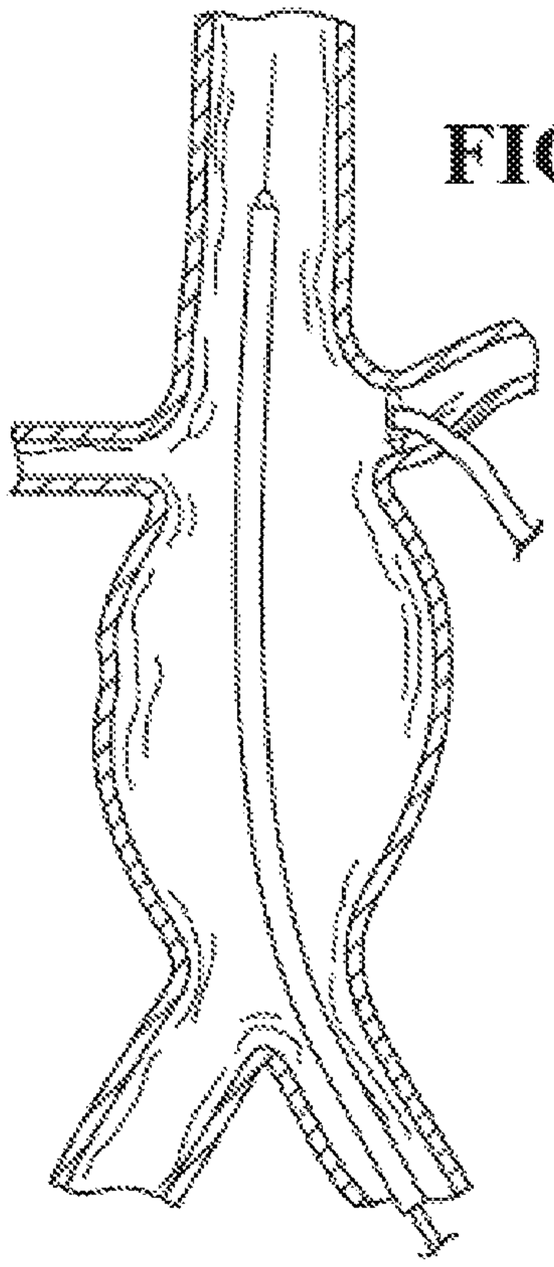

FIG. 6E-1

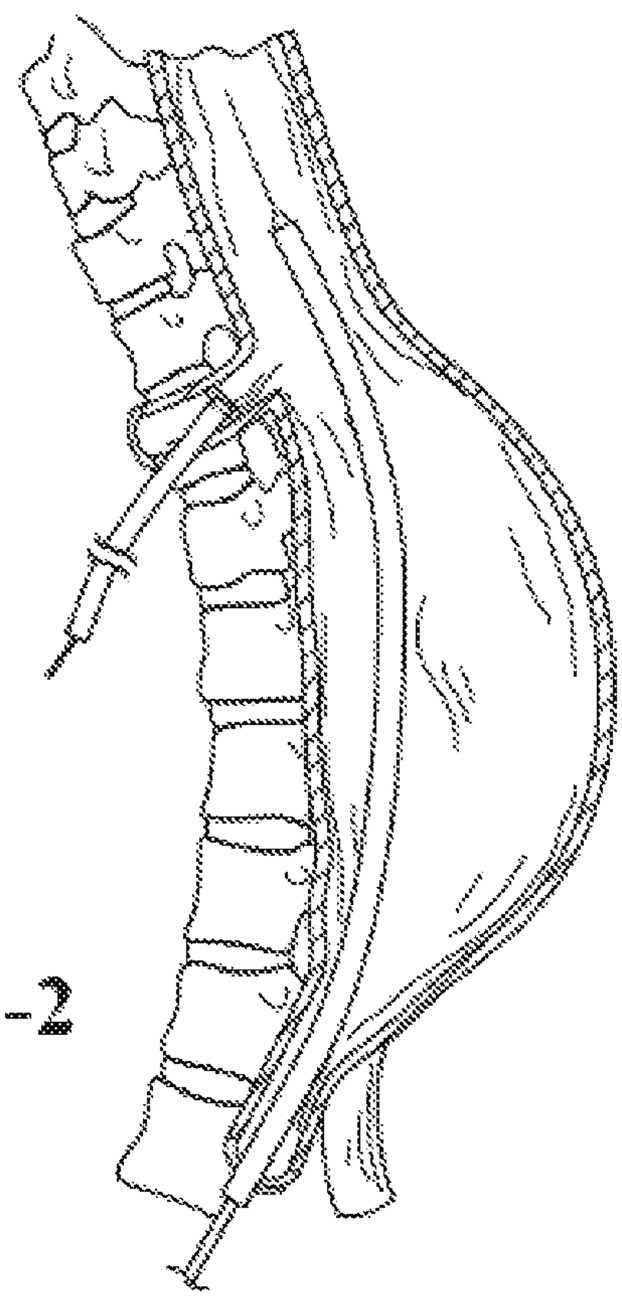

FIG. 6E-2

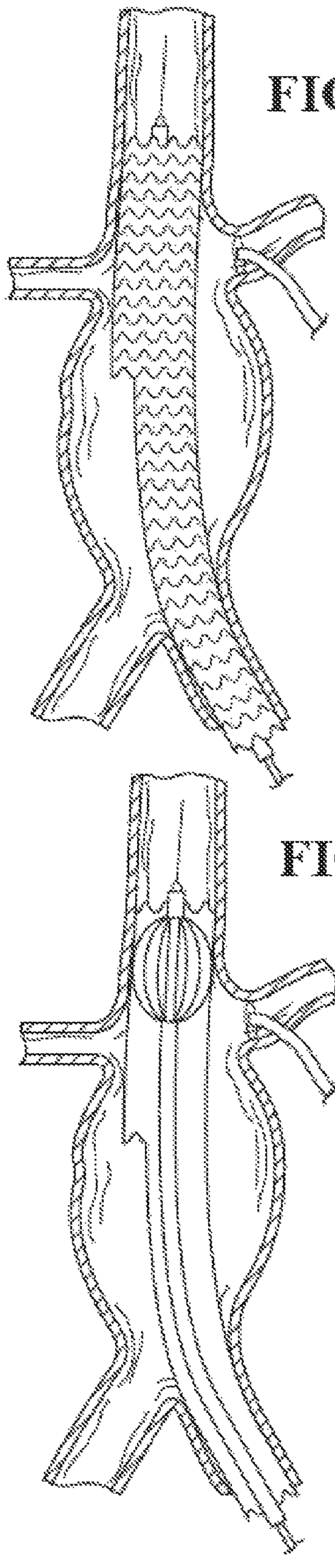

FIG. 6F-1

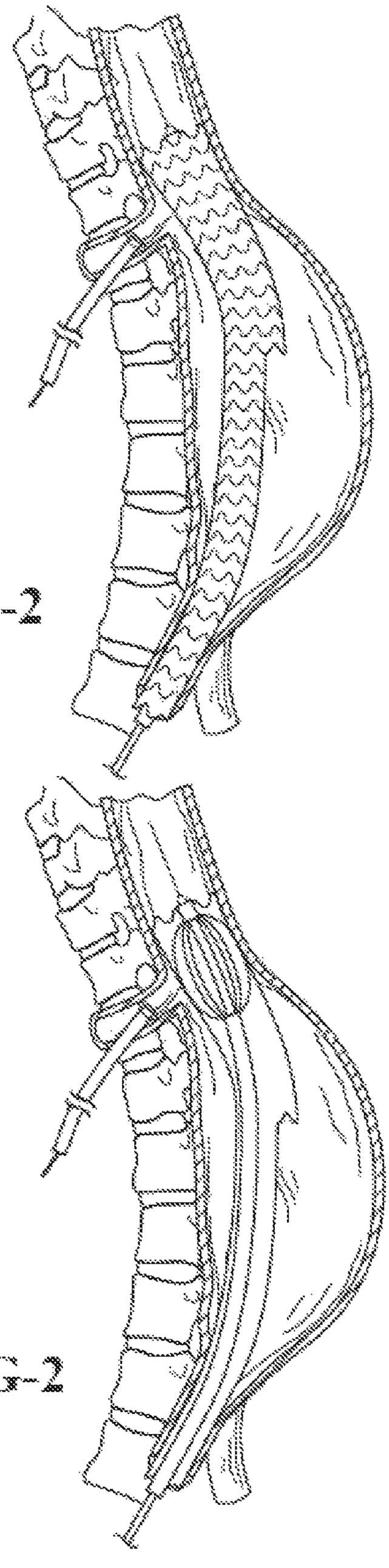

FIG. 6F-2

FIG. 6G-1

FIG. 6G-2

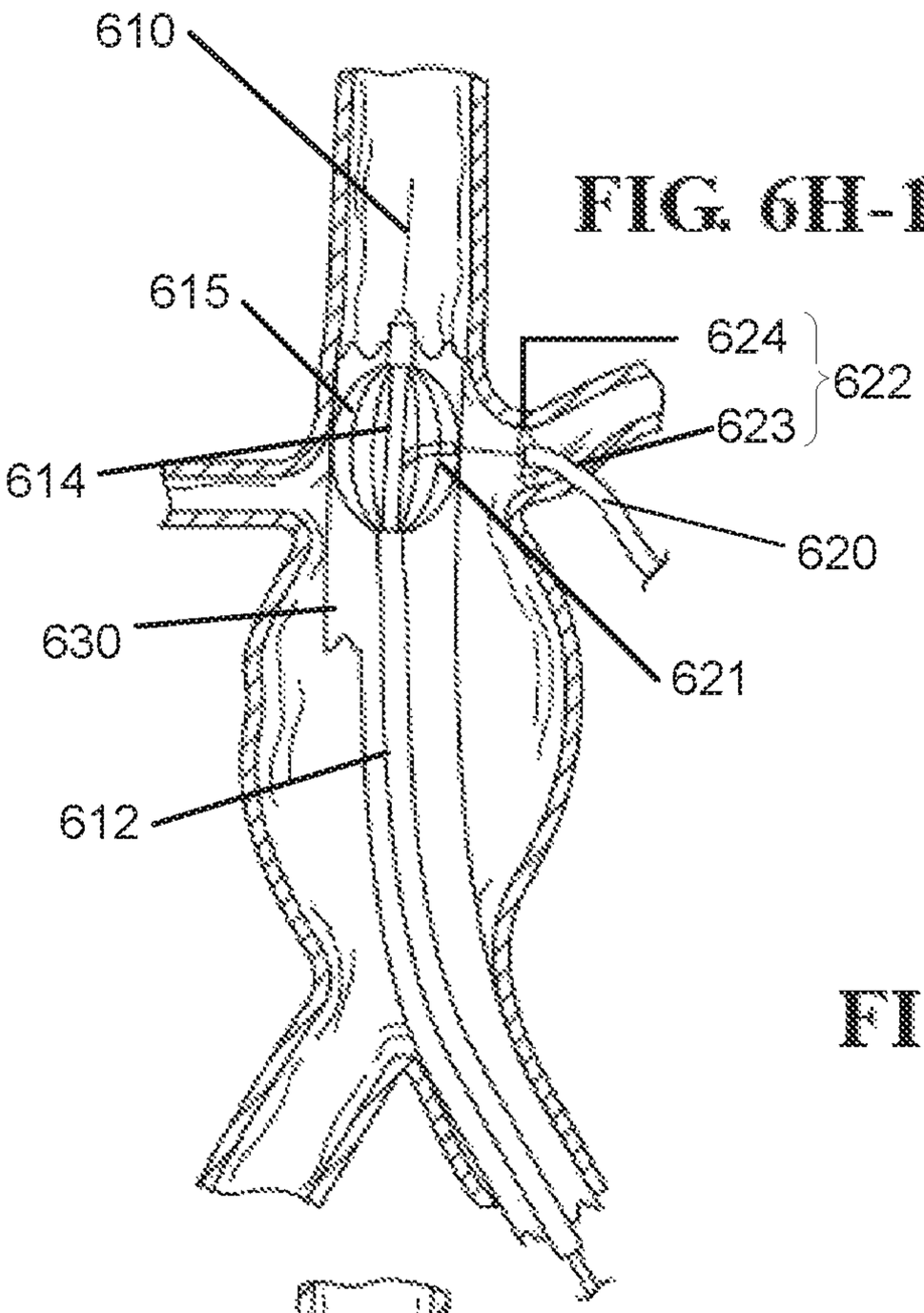

FIG. 6H-1

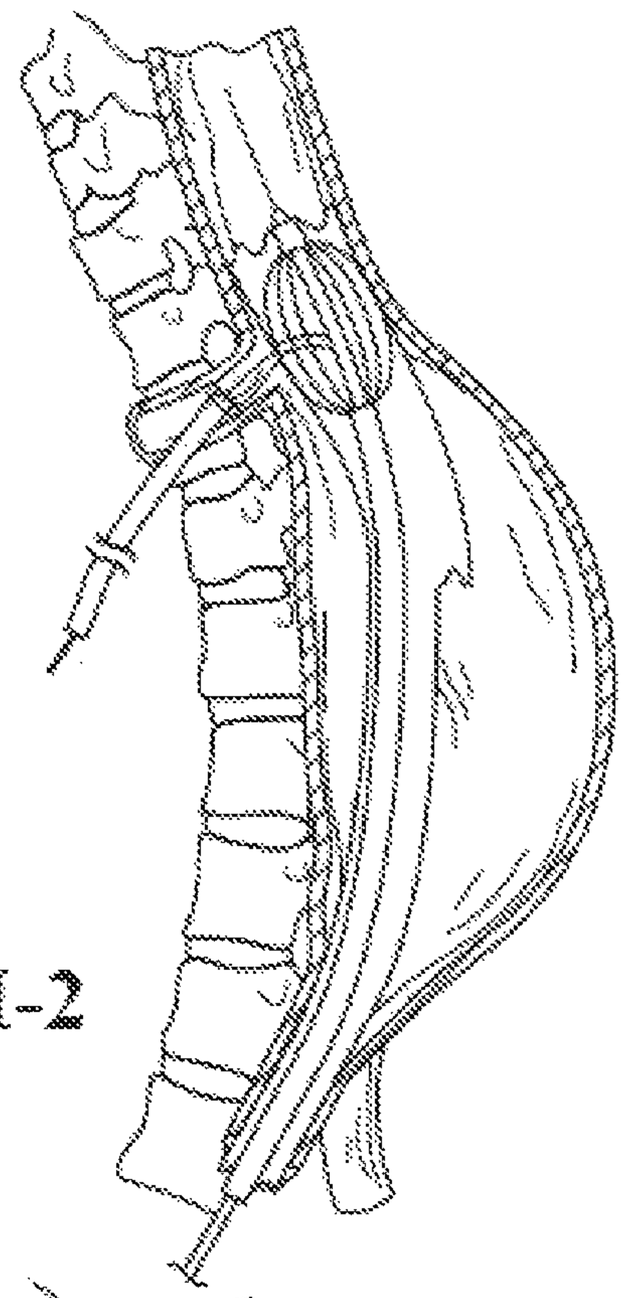

FIG. 6H-2

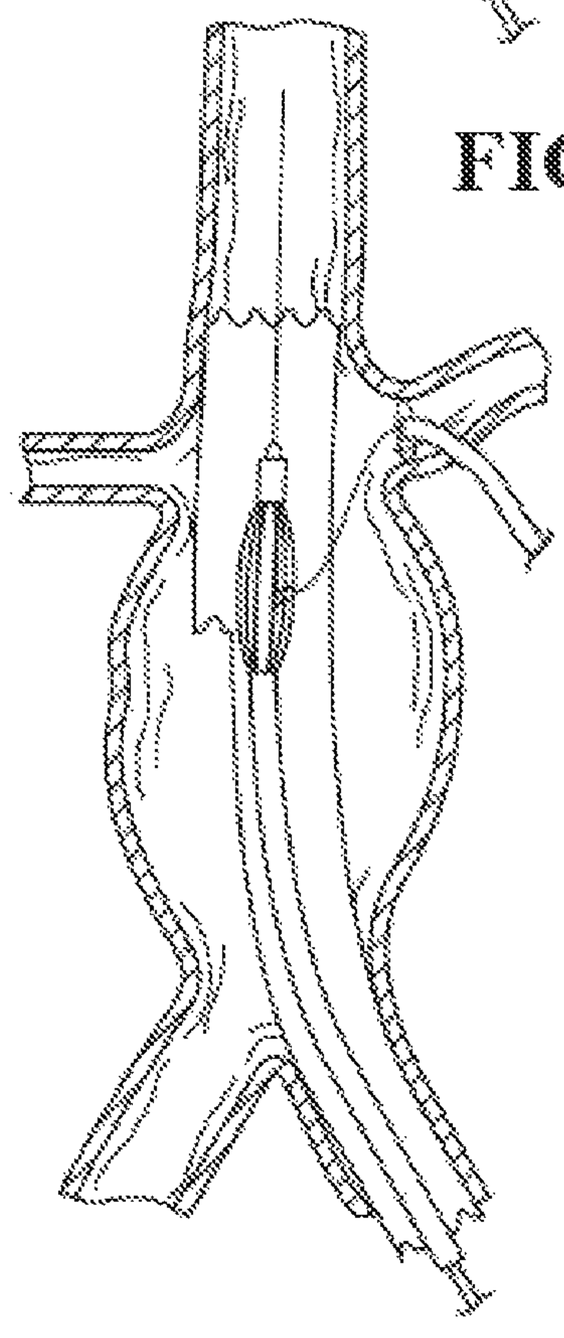

FIG. 6I-1

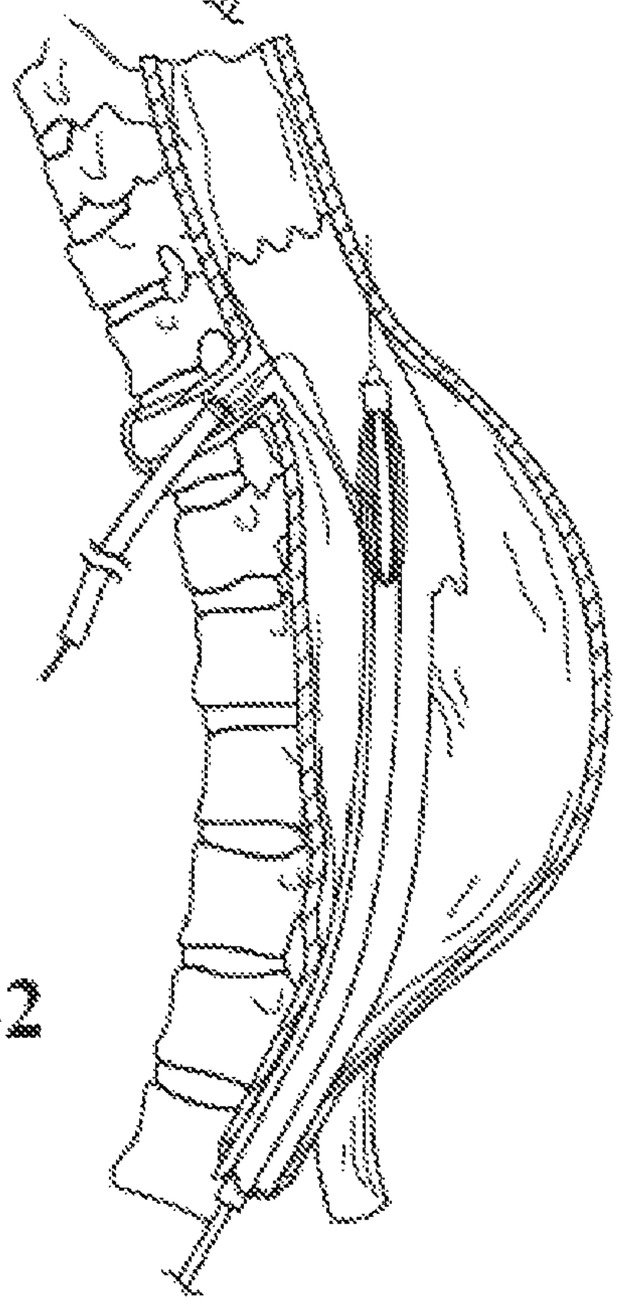

FIG. 6I-2

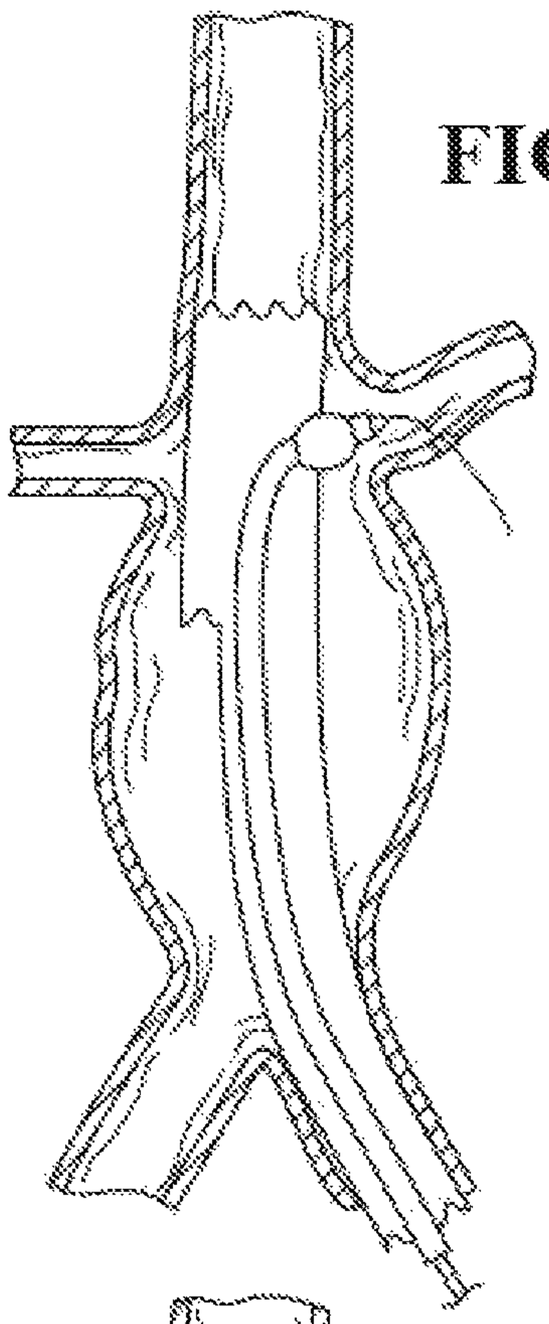

FIG. 6J-1

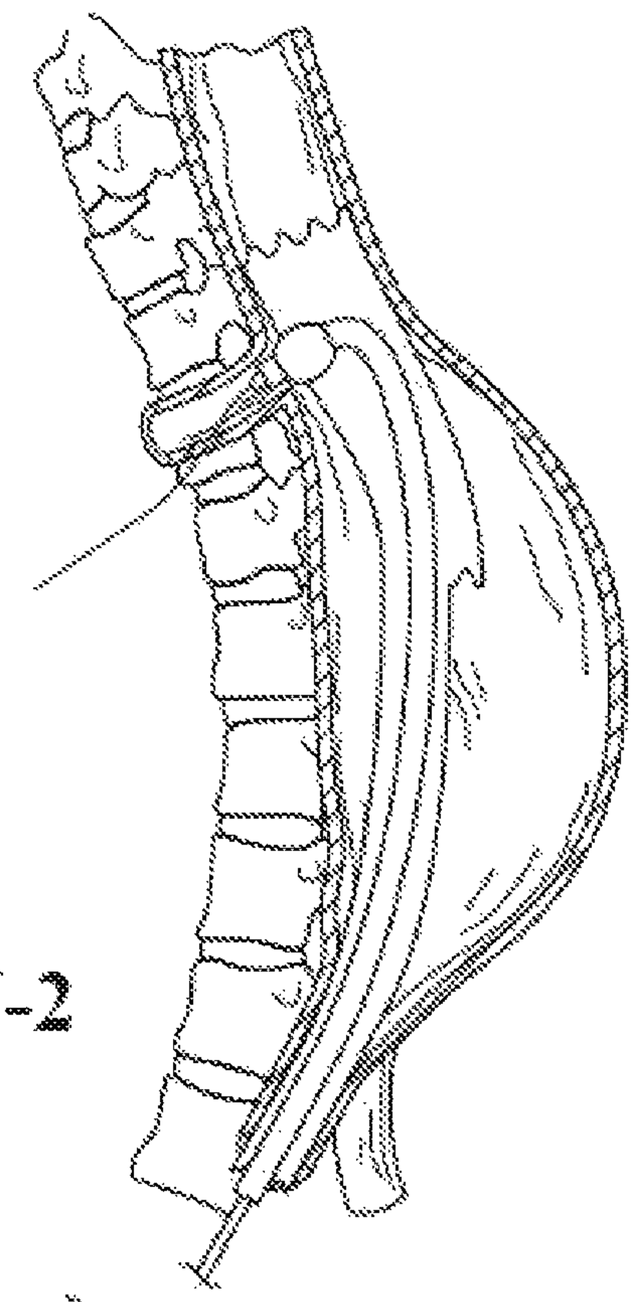

FIG. 6J-2

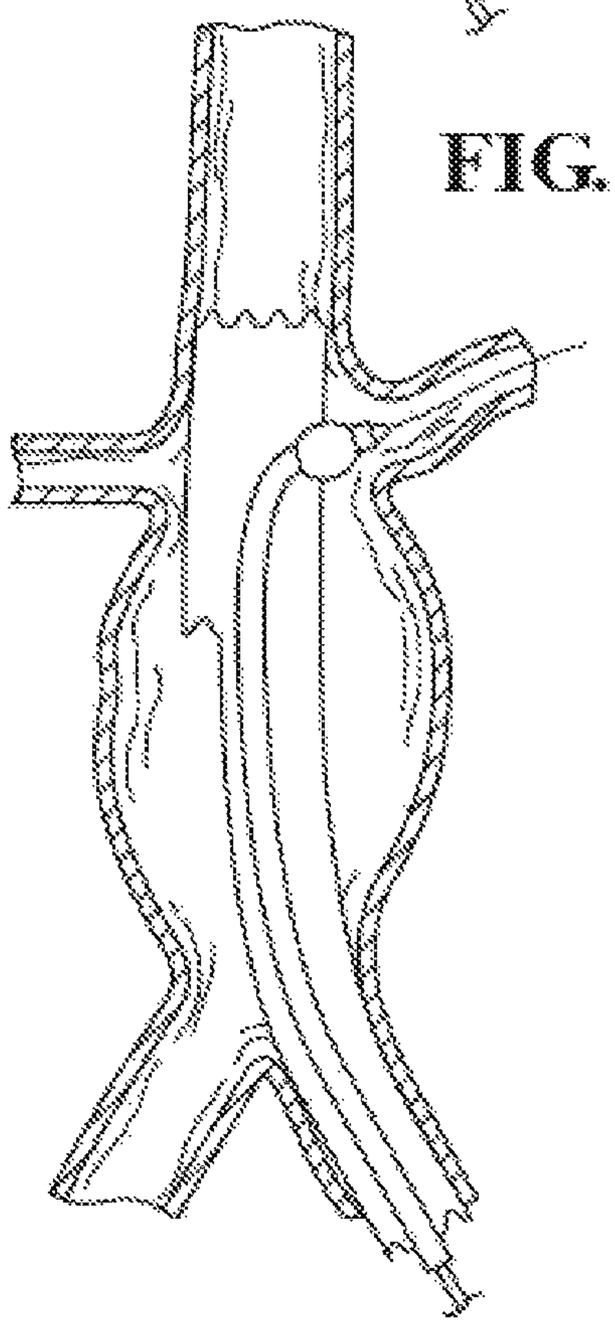

FIG. 6K-1

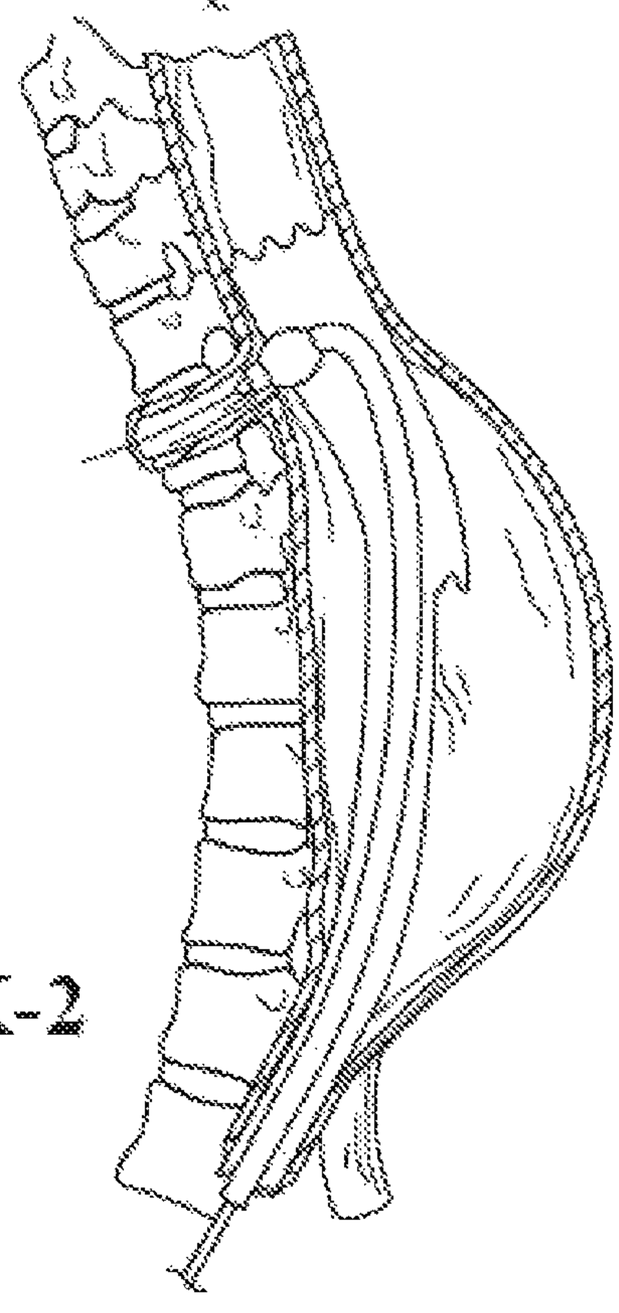

FIG. 6K-2

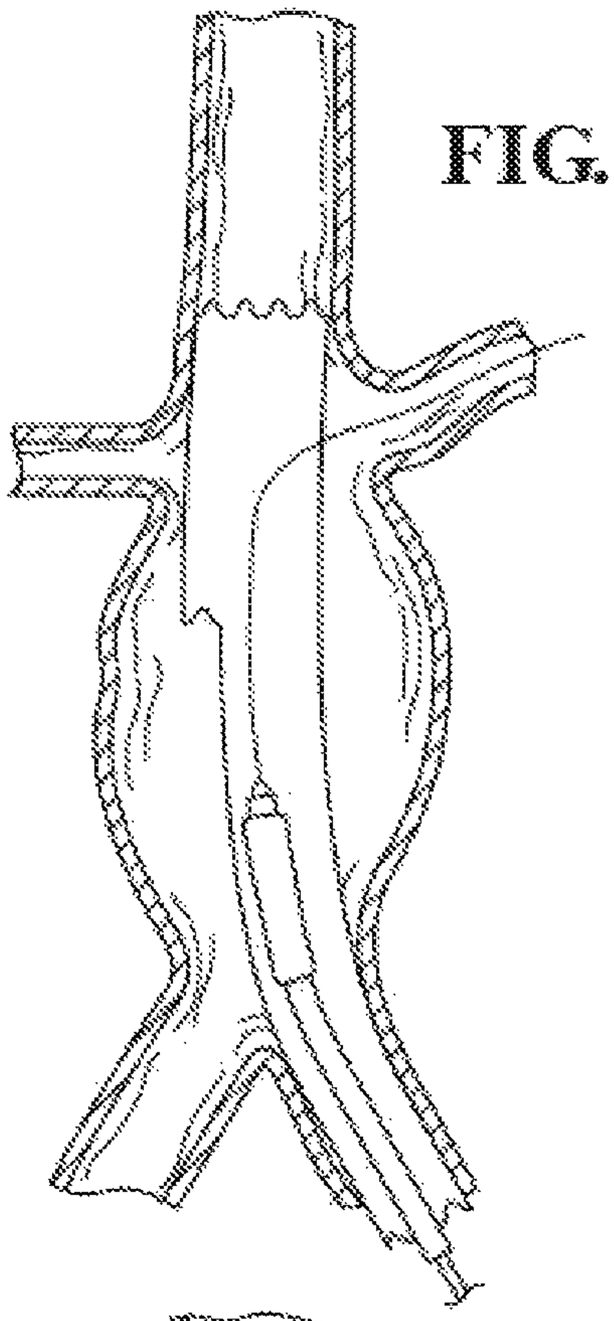

FIG. 6L-1

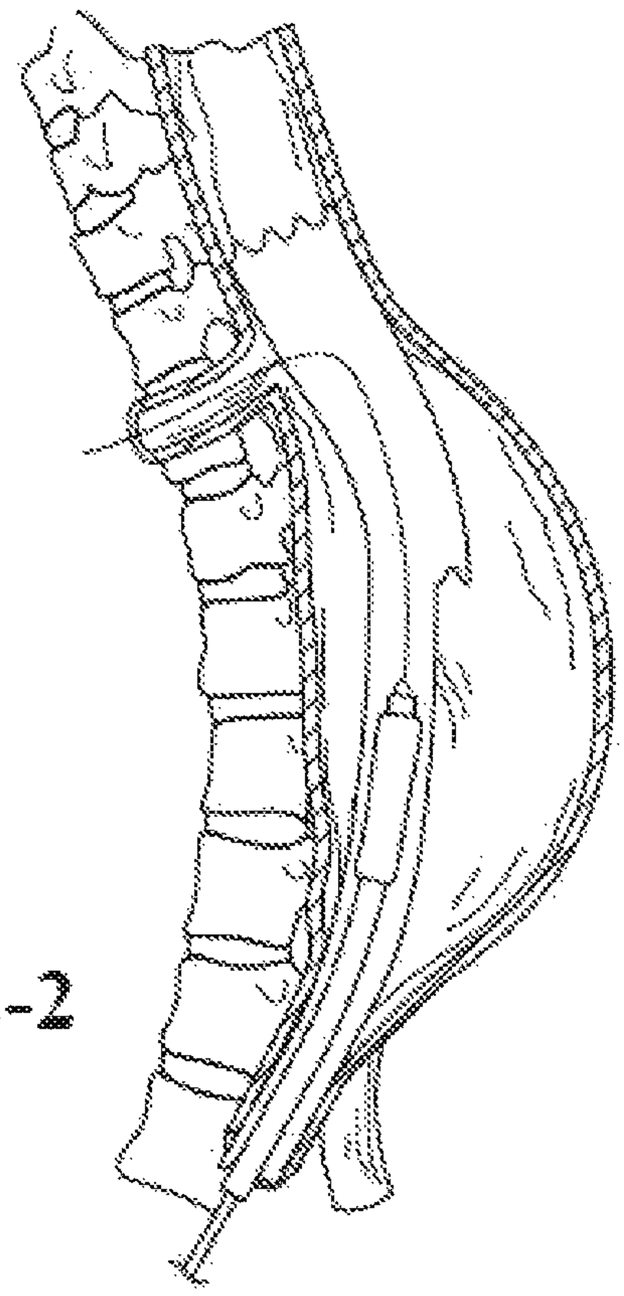

FIG. 6L-2

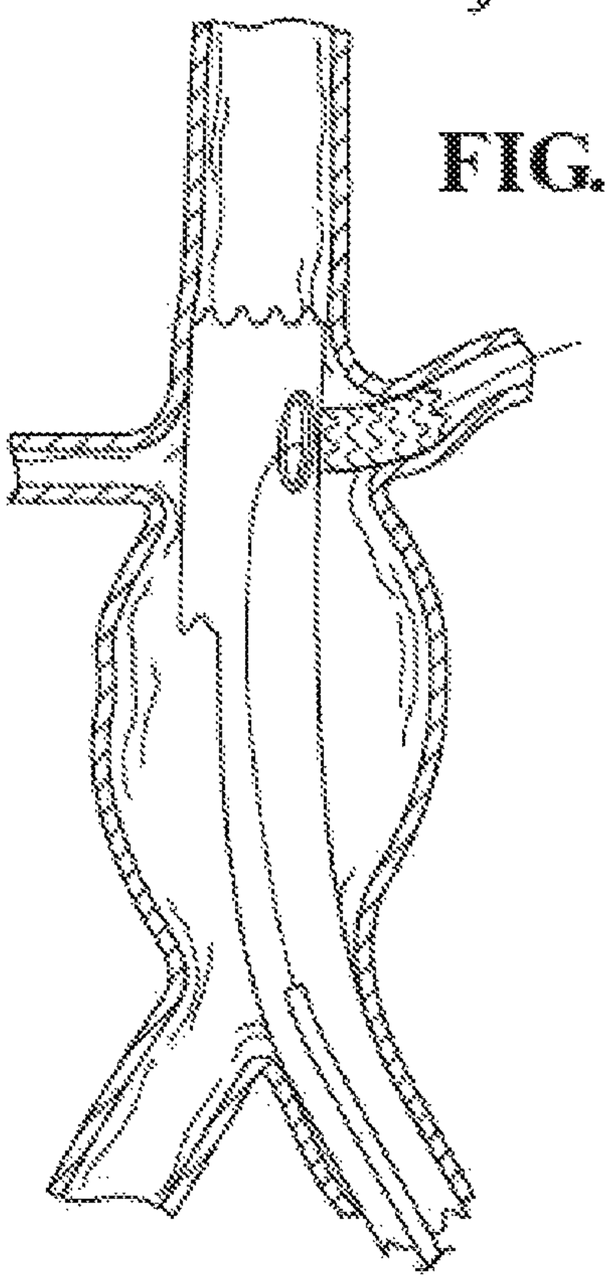

FIG. 6M-1

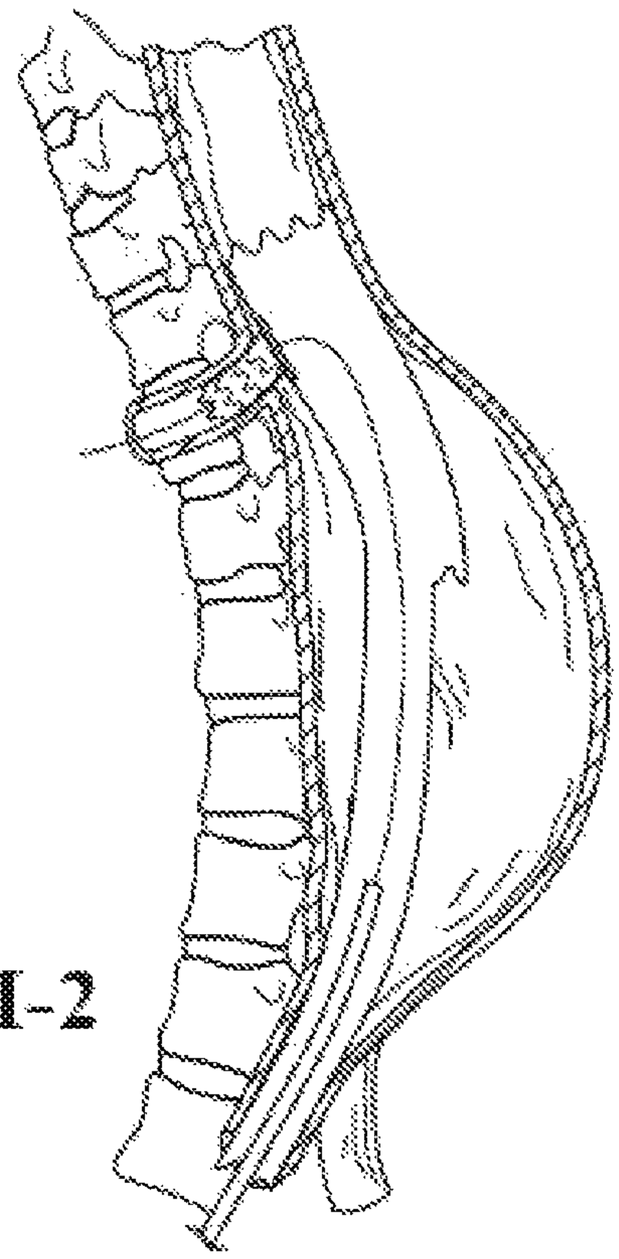

FIG. 6M-2

FENESTRATION DEVICES, SYSTEMS, AND METHODS

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of Ser. No. 13/295,817, filed Nov. 14, 2011, under 35 U.S.C. § 120, which claims the benefit of U.S. Provisional Patent Application No. 61/414,155 filed on Nov. 16, 2010, the disclosures of each of which are hereby incorporated by reference in their entirety.

BACKGROUND

Field

The present disclosure relates to the field of endoluminal products, and more particularly, to the field of fenestration devices, systems, and methods.

Discussion of the Related Art

Endovascular surgery is a minimally invasive method of treating vascular diseases from inside the blood vessel. Benefits of minimally invasive procedures include shorter hospital stays, quicker recoveries, and lower risk of complications. Difficulties with endovascular procedures include traversing irregularly shaped, highly tortuous, heavily branched, and very narrow vessels to gain access to the treatment site, and once access is gained, difficulties further include fine-tuning the rotational and lateral position of the tool. Another difficulty relates to maintaining continued blood flow through the vessels during the course of treatment.

When a stent graft is deployed, branch vessels in the proximity of the stent graft can become sealed off from the flow of blood. In order to maintain blood flow, the graft must be fenestrated at the branch vessel junction. This can be problematic because stent graft materials are typically very strong and durable in order to survive conditions within a mobile host vessel for many years, and puncturing this durable material endovascularly adds to the difficulty of the task. Procedures within the aorta present even more challenges, as compared to other vascular treatment sites, because the size and shape of the aorta and the dynamics of blood flow.

Safe preservation of blood flow to the supra-aortic branches during the procedure and subsequently is desirable. In situ fenestration of aortic devices has the potential to allow for continued perfusion of supra-aortic branches, without the need for extra-anatomic bypass, and without the need for custom-made devices. The angle formed by the branch vessel relative to the main vessel is an obstacle to success with this technique

Therefore, a need exists to develop better devices, systems, and methods for endovascular treatment of vessels that permit more accurate positioning and continued blood flow, especially with respect to in situ fenestration of aortic devices. In addition, a need exists for incorporating multiple tools within a single device capable of accurate positioning and continued blood flow that canalize the selected sites.

SUMMARY

The present disclosure is generally directed toward devices, systems and methods for guiding an endovascular tool, such as a puncturing tool or an angioscope, in a radial or askew direction, such as toward or through the sidewall of a vessel or a stent device, as that term is defined herein, using cooperative elongate members. The present disclosure is generally directed toward devices, systems and methods for locating branch vessels from within a grafted main vessel and directing endovascular tools to the branch-main vessel junction. Illustrative embodiments may be useful to pierce grafts or stent-grafts to create fenestrations. Illustrative embodiments may be useful to treat aneurysms, dissections, and other pathologies located in the aortic arch. Illustrative embodiments may be useful in connection with the treatment of coronary artery disease, peripheral vascular diseases, portal hypertension, carotid artery disease, renal vascular hypertension, amongst other conditions affecting anatomical conduits. Illustrative embodiments may also be useful to deliver drugs or other implantable devices to specific treatment sites.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings provide a further understanding of the present disclosure and are incorporated in and constitute a part of this specification, illustrate embodiments of the disclosure, and together with the description serve to explain the principles of the disclosure.

FIG. **1**A illustrates a perspective view of an embodiment in a collapsed position;

FIG. **1**B illustrates a side view of an embodiment in a collapsed position;

FIG. **2**A illustrates a side view of an embodiment in an expanded position;

FIG. **2**B illustrates a perspective view of an embodiment in an expanded position;

FIG. **3** illustrates a cross-section at a side view of an embodiment in an expanded position;

FIG. **4** illustrates a perspective view of an embodiment in an expanded position with a fenestration tool deployed through the distal end of a third elongate member;

FIGS. **5**A-**1** and **5**A-**2** illustrate a cross-section view of an embodiment of an endovascular target with a inflatable distal anchor positioned in a branch vessel and a side view of the endovascular target;

FIGS. **5**B-**1** and **5**B-**2** illustrate a cross-section view of an embodiment of an endovascular target with a helical distal anchor positioned in a branch vessel and a side view of the endovascular target; and

FIGS. **6**A-**1**, **6**A-**2**, **6**B-**1**, **6**B-**2**, **6**C-**1**, **6**C-**2**, **6**D-**1**, **6**D-**2**, **6**E-**1**, **6**E-**2**, **6**F-**1**, **6**F-**2**, **6**G-**1**, **6**G-**2**, **6**H-**1**, **6**H-**2**, **6**I-**1**, **6**I-**2**, **6**J-**1**, **6**J-**2**, **6**K-**1**, **6**K-**2**, **6**L-**1**, **6**L-**2**, **6**M-**1**, and **6**M-**2** illustrate steps of an embodiment to stent a main vessel and a branch vessel.

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

Persons skilled in the art will readily appreciate that various aspects of the present disclosure may be realized by any number of methods and apparatuses configured to perform the intended functions. Stated differently, other methods and apparatuses may be incorporated herein to perform the intended functions. It should also be noted that the accompanying drawing figures referred to herein are not all drawn to scale, but may be exaggerated to illustrate various aspects of the present disclosure, and in that regard, the drawing figures should not be construed as limiting. Finally, although the present disclosure may be described in

connection with various principles and beliefs, the present disclosure should not be bound by theory.

The terms "proximal" and "distal," when used herein in relation to a device or device component refer to directions closer to and farther away from the operator of the device. Since the present disclosure is not limited to peripheral or central approaches, the device should not be narrowly construed when using the terms proximal or distal since device features may be slightly altered relative to the anatomical features and the device position relative thereto.

The present disclosure is directed toward devices, systems and methods for guiding an endovascular tool, such as a puncturing tool or an angioscope, in a radial or askew direction, such as toward or through the sidewall of a vessel or a stent device, as that term is defined herein using elongate members and specialized catheters. The present disclosure is directed toward devices, systems and methods for locating branch vessels from within a grafted main vessel and directing endovascular tools to the branch-main vessel junction. Illustrative embodiments may be useful to pierce grafts or stent-grafts to create fenestrations. Illustrative embodiments may be useful to treat aneurysms, dissections, and other pathologies located in the aortic arch. Illustrative embodiments may be useful in connection with the treatment of coronary artery disease, peripheral vascular diseases, portal hypertension, carotid artery disease, renal vascular hypertension, amongst other conditions affecting anatomical conduits. Illustrative embodiments may also be useful to deliver drugs and other implantable devices to specific treatment sites.

As used herein, a "vessel" may be an artery, vein, capillary or the like, or any other anatomical passageway such as stomach or intestine, conduit or lumen existing in a healthy subject. As used herein, "connected" means to join, couple, attach two or more elements whether directly or indirectly, whether permanently or temporarily. As used herein, a "stent device" may refer to a graft, a stent, stent graft, or any other device that may require a fenestration.

In accordance with an embodiment, a guide device is deployable through a vessel to a treatment site. The guide device deploys an endovascular tool to the treatment site and directs or channels the tool in a direction generally normal or off axis to the longitudinal axis of a stent device. In a further embodiment, the guide device may be detectable within the body with the use of ex vivo detectors, thereby facilitating the generally accurate positioning of the guide device.

A guide device may comprise an expandable member configured to expand radially and a guide tube operatively coupled to the expandable member to channel or guide an endovascular tool in an askew, generally radial, or generally orthogonal direction. Askew, as used herein, describes a direction that is generally at an angle from the path of delivery. In an embodiment, the expandable member bends or extends outwardly and thus expands in response to a compression force that may be applied via the longitudinal displacement of an elongate member relative to another elongate member. In other embodiments, an inflatable member may facilitate the expansion of the expandable member. The distal end of the guide tube or other portions may comprise radiopaque material to facilitate generally accurate positioning within the body.

Method of use may comprise deploying through a vessel the guide device to a treatment site, and may further comprise outwardly extending or expanding an expandable member and channeling a subsequent tool (e.g., for puncture, cannulation, etc.) to the selected target. The guide device may be positioned with the use of a detector. An endovascular tool may be deployed through the guide device to the selected treatment site.

Other aspects of the present disclosure involve endovascular targets that are configured to anchor into a branch vessel and facilitate fenestration of an aortic graft, stent, or stent graft while maintaining continuous aortic downstream perfusion throughout the stent deployment and fenestration.

Another aspect involves a reverse cannulation system, particularly useful for stenting the abdominal aorta proximate the renal arteries and stenting the renal artery. An embodiment of the system comprises a puncturing tool entering and piercing a stent graft from the renal artery side, a snare device entering from the abdominal aorta side. The snare device captures the puncture tool and pulls the tool with its accompanying guidewire through to the abdominal aorta access point. A stent device is deployed along this guide wire to stent the renal artery.

Persons skilled in the art will appreciate that the embodiments described herein may be useful in, amongst other things, endovascular treatments to remotely turn or angle endovascular tools with some degree of precision, to make in-situ fenestrations at an angle, to pierce sidewalls of strong, durable graft material in-situ, to maintain the perfusion of branch vessels, and to cross or create one or more ducts through a wide variety of anatomical features.

In accordance with an embodiment, and with reference to FIGS. **1**A, **1**B, **2**A and **2**B, a guide device **200** may be structurally or materially configured to deploy an endovascular tool or implant to the treatment site and channel the tool in a direction **251** generally radial, generally orthogonal, or otherwise off axis from its path of delivery **250**. An "endovascular tool" comprises any tool capable of use in endovascular procedures, such as a puncturing tool as described herein, piercing catheter, re-entry device, dual-lumen re-entry device, an angioscope, an elongate member, a guide device as described herein, an endovascular target as described herein, a stent, a stent graft, a drug delivery tool, amongst other endovascular tools, and combinations thereof. Exemplary "piercing catheters," "re-entry devices," "dual-lumen re-entry devices," and combinations thereof are more fully described in U.S. patent application Ser. No. 13/273,111 to Cully et al., entitled "System and Method of Percutaneous Occlusion Crossing," hereby incorporated by reference in its entirety.

In accordance with an embodiment, guide device **200** comprises an expandable member **210** and a guide tube **240** operatively coupled to expandable member **210** and having a distal tip **241**, which is moveable between a first position generally parallel with expandable member **210** in a collapsed position and a second position askew to the first position.

Expandable member **210** comprises a radially expandable or outwardly extending structure that is moveable between a collapsed position and an expanded position. Expandable member **210** may be structurally or materially configured to expand such that guide tube **240** operatively coupled thereto radially extends in an askew or generally orthogonal direction. Expandable member **210** may also be structurally or materially configured such that at least some continuous blood flow is maintained, e.g., with only minor disruption to flow, while the expandable member **210** is in its expanded position and/or during the transition to the expanded position. Expandable member **210** may be structurally or materially configured to provide additional support to the vessel at a treatment site, for example, by expanding in such a way as to contact vessel walls. In addition, expandable member

210 may be structurally or materially configured to snare an elongate member. In this regard, FIGS. 2A and 2B illustrate an embodiment having an expandable member 210 in a expanded position and FIGS. 1A and 1B illustrate an embodiment having an expandable member 210 in a collapsed position

Expandable member 210 may be structurally or materially configured to be moveable between a collapsed position and an outwardly extending, expanded position. In addition, expandable member may be selectively actuated between the two positions. Expandable member 210 may be slideably actuated, inflatably actuated, self-expanding, spring actuated, combinations of the same, or actuated via any other mode of actuation.

In accordance with an embodiment, a guide device is deployable through a vessel to a treatment site. The guide device deploys an endovascular tool to the treatment site and channels the tool in a direction generally normal or off axis to the longitudinal axis of a stent device. In a further embodiment, the guide device may be detectable within the body with the use of ex vivo detectors, thereby facilitating the generally accurate positioning of the guide device.

A guide device may comprise an expandable member configured to expand radially and a guide tube operatively coupled to the expandable member to channel in an endovascular tool in an askew, generally radial, or generally orthogonal direction. Askew, as used herein, describes a direction that is generally at an angle from the path of delivery. In an embodiment, the expandable member bends or extends outwardly and thus expands in response to a compression force that may be applied via the longitudinal displacement of an elongate member relative to another elongate member. In other embodiments, an inflatable member may facilitate the expansion of the expandable member. The distal end of the guide tube or other portions may comprise radiopaque material to facilitate generally accurate positioning within the body.

Method of use may comprise deploying through a vessel the guide device to a treatment site, and may further comprise outwardly extending or expanding an expandable member and channeling a subsequent tool (e.g., for puncture, cannulation, etc.) to the selected target. The guide device may be positioned with the use of a detector. An endovascular tool may be deployed through the guide device to the selected treatment site.

Other aspects of the present disclosure involve endovascular targets that are configured to anchor into a branch vessel and facilitate fenestration of an aortic graft, stent, or stent graft while maintaining continuous aortic downstream perfusion throughout the stent deployment and fenestration.

Another aspect involves a reverse cannulation system, particularly useful for stenting the abdominal aorta proximate the renal arteries and stenting the renal artery. An embodiment of the system comprises a puncturing tool entering and piercing a stent graft from the renal artery side, a snare device entering from the abdominal aorta side. The snare device captures the puncture tool and pulls the tool with its accompanying guidewire through to the abdominal aorta access point. A stent device is deployed along this guide wire to stent the renal artery.

For example, expandable member 210 may be slideably actuated to an expanded position. Such expansion may be in response to corresponding longitudinal displacement of a second elongate member 230 relative to a first elongate member 220, which applies a compression force or tension force to expandable member 210. As such, expandable member 210 at a first end may be connected to first elongate member 220, and the opposite second end is connected to second elongate member 230, such that expandable member 210 is deformed generally radially in response to selective axial displacement of second elongate member 230 relative to first elongate member 220. Collapsing expandable member 210 may be performed by selective axial displacement opposite that required to expand.

In such an embodiment, first elongate member 220 may comprise a first lumen, and second elongate member 230 may comprise a second lumen and a side opening 231. Second elongate member 230 may be disposed along the first lumen, and side opening 231 may be adjacent to expandable member 210. In one embodiment, guide tube 240 may be slideably housed along the second lumen of second elongate member 230, and guide tube 240 may pass through side opening 231 to connect with expandable member 210. For example, FIG. 3 illustrates a cross-sectional view of guide tube 340 disposed along the lumen of second elongate member 330. In an alternative embodiment, a second elongate member does not comprise a side opening. In such an embodiment, the guide tube is slideably housed in the first elongate member lumen and disposed alongside the second elongate member.

As used herein, an "elongate member" has proximal and distal ends and is capable of passing through a vessel. Typically, an elongate member is flexible, especially when an elongate member is required to traverse through tortuous vasculature. Examples include a guidewire, catheter, optical fiber, or the like. An elongate member may comprise a lumen over the entire distance or a part thereof or may be solid throughout. An elongate member may comprise a blunt, rounded, or tapered distal tip, to name a few, and may be characterized by varying degrees of rigidity or softness, which may further vary along the length of the elongate member. Elongate members may have any cross-sectional shape including circular, oval, triangular, square, polygon shaped or randomly shaped. An elongate member, or any portion thereof, may be hydrophilic or hydrophobic. As used herein, a "catheter" and/or "tube" is an elongate member comprising a lumen extending through from the proximal end to the distal end.

Typical materials used to construct an elongate member can comprise materials such as Amorphous Commodity Thermoplastics that include Polymethyl Methacrylate (PMMA or Acrylic), Polystyrene (PS), Acrylonitrile Butadiene Styrene (ABS), Polyvinyl Chloride (PVC), Modified Polyethylene Terephthalate Glycol (PETG), Cellulose Acetate Butyrate (CAB); Semi-Crystalline Commodity Plastics that include Polyethylene (PE), High Density Polyethylene (HDPE), Low Density Polyethylene (LDPE or LLDPE), Polypropylene (PP), Polymethylpentene (PMP); Amorphous Engineering Thermoplastics that include Polycarbonate (PC), Polyphenylene Oxide (PPO), Modified Polyphenylene Oxide (Mod PPO), Polyphenylene Ether (PPE), Modified Polyphenylene Ether (Mod PPE), Thermoplastic Polyurethane (TPU); Semi-Crystalline Engineering Thermoplastics that include Polyamide (PA or Nylon), Polyoxymethylene (POM or Acetal), Polyethylene Terephthalate (PET, Thermoplastic Polyester), Polybutylene Terephthalate (PBT, Thermoplastic Polyester), Ultra High Molecular Weight Polyethylene (UHMW-PE); High Performance Thermoplastics that include Polyimide (PI, Imidized Plastic), Polyamide Imide (PAI, Imidized Plastic), Polybenzimidazole (PBI, Imidized Plastic); Amorphous High Performance Thermoplastics that include Polysulfone (PSU), Polyetherimide (PEI), Polyether Sulfone (PES), Polyaryl Sulfone (PAS); Semi-Crystalline High Performance Ther-

moplastics that include Polyphenylene Sulfide (PPS), Polyetheretherketone (PEEK); and Semi-Crystalline High Performance Thermoplastics, Fluoropolymers that include Fluorinated Ethylene Propylene (FEP), Ethylene Chlorotrifluroethylene (ECTFE), Ethylene, Ethylene Tetrafluoroethylene (ETFE), Polychlortrifluoroethylene (PCTFE), Polytetrafluoroethylenes (PTFEs), expanded Polytetrafluoroethylenes (ePTFEs), Polyvinylidene Fluoride (PVDF), Perfluoroalkoxy (PFA). Other commonly known medical grade materials include elastomeric organosilicon polymers, polyether block amide or thermoplastic copolyether (PEBAX) and metals such as stainless steel and nickel/titanium alloys.

With reference back to FIGS. **1**A, **1**B, **2**A, and **2**B, another expansion mechanism may comprise inflatable actuation, such as via an inflatable member. For example, guide device **200** may comprise a balloon locatable within expandable member **210** that upon inflation outwardly extends expandable member **210**. The inflatable member may be deflated and then confined by expandable member **210** when expandable member **210** transitions back to its collapsed position for withdrawal.

Alternatively, expandable member **210** may be made to self-expand upon release from a constraining mechanism such as a sheath. In such embodiments, expandable member **210** may be fabricated from shape-memory alloys or polymers such as stainless steel (SST), nitinol, polyurethanes, or the like such that it is configured as a passively expanding device. Guide device **200** may comprise any configuration or materials that facilitate expandable member **210** movement between its collapsed position and its outwardly extending expanded position.

In an embodiment, expandable member **210** may comprise bendable elements that are outwardly extendable. In addition, expandable member **210** may comprise a discontinuous or open structure when in the expanded position. A discontinuous or open structure permits fluid to flow across expandable member **210** with only minor fluid disruption. Maintaining downstream perfusion also relates to cannulation accuracy in the fact that guide device **200** need not withstand or resist pressures associated with temporary occlusion. For example, expandable member **210** may comprise bendable elements that separate from each other, creating space therebetween, as these elements outwardly extend, such as a malecot structure, mesh member, or a flexible tube with diagonal or longitudinal slits. Similarly, expandable member **210** may comprise at least one slat **211** connected at one end to first elongate member **220** and connected at the other end to second elongate member **230**. Expandable member **210** may be integral with first elongate member **220**, second elongate member **230**, or a separate structure connected thereto.

The expansion of expandable member **210** may be radially symmetrical or only occur about a fraction of the perimeter of expandable member **210** creating radial asymmetry. Moreover, the distance that expandable member **210** expands or outwardly extends from the longitudinal axis may vary about the perimeter of expandable member **210** or be uniform. Such variations providing an asymmetrical profile to expandable member **210** may yield various benefits such as a wider turning radius or greater flexibility in the types of endovascular tools deployable through guide tube **240**. For example, in an embodiment, expandable member **210** may comprise different materials with varying degrees of rigidity such that one side of expandable member **210** outwardly extends more so than the opposite side.

Expandable member **210** comprises a flexible material that is sufficiently rigid and strong enough to outwardly extend distal tip **241** and maintain its expanded position during a procedure. In addition, expandable member **210** may comprise a material that is sufficiently rigid to support the vessel wall during a procedure, such as a fenestration procedure. Expandable member **210** may have a generally curved profile when in an expanded position to minimize vessel wall trauma about any points of contact. Expandable member **210** may be comprised of any number of biocompatible materials including nitinol, silicon, latex, polyurethane, polyvinyl chloride, polysiloxanes, polycarbonate, polyethylene, nylon, PTFEs (e.g., ePTFEs), stainless steel, or any biocompatible material, including combinations of the foregoing.

The width or diameter of expandable member **210** in its expanded position may be adjustable across a range of widths or diameters. For example, the expandable member **210** in its expanded position may comprise a range of widths or diameters within the following values: about 1 mm to about 65 mm, about 2 mm to about 45 mm, or about 3 mm to about 30 mm. As such, guide device **200** of a certain configuration may be adaptable to a variety of vessel diameters. Similarly, guide device **200** may be scaleable, and thus, utilized in a variety of applications, such as procedures in the peripheral vasculature.

Expandable member **210** may comprise a radiopaque, echogenic, or magnetic material, or any other material capable of ex vivo detection. This material may be an integral part of member **210**, a coating, or a separate marker connected thereto.

In various embodiments, expandable member **210** may be configured to be a vessel diameter-measuring device. For example, guide device **200** may comprise a calibrated scale on the proximal end of second elongate member **230** so that the degree of expansion correlates to an axial position on second elongate member **230**. Knowing the vessel diameter can assist with determining the appropriate diametrical size of the stent or stent graft to utilize. In addition, applying an internally distensive force while measuring the vessel diameter may further assist in selecting a stent or stent graft. The force applied by the device during measurement should correlate to the force applied by a stent or stent graft in the same place.

Guide tube **240** may be operatively coupled or connected to expandable member **210** such that when expandable member **210** moves to its expanded position, distal tip **241** radially or outwardly extends therewith. Guide tube **240** may be connected such that an endovascular tool may pass through the distal end of guide tube **240**. As such, expandable member **210** may comprise an aperture **213**. Aperture **213** is any opening located on expandable member **210** that permits an endovascular tool to pass through guide tube **240** with obstruction from expandable member **210**. Guide tube **240** may be connected to expandable member **210** such that the distal exit of guide tube **240** is coincident the aperture **213**. In other embodiments, in lieu of an aperture **213**, the guide tube may be tangentially connected to expandable member **210** such that an endovascular tool may pass through guide tube **240**.

In an embodiment, guide tube **240** comprises any structure configured to guide an endovascular tool to a site radial, generally orthogonal, or otherwise askew or off-axis the path of delivery **250**. For example, guide tube **240** can comprise an elongate member having a proximal and distal end with a lumen therethrough Alternatively, guide tube can comprise a half tube, trough, or some other rail- or track-like con-

figuration to guide the endovascular tool in an askew direction. In addition, guide tube **240** may direct an endovascular tool, such as that described in U.S. patent application Ser. No. 13/273,111 to Cully et al., in a substantially orthogonal direction or substantially constant angle throughout the range of expanded position diameters or widths.

Guide tube **240** may be modified to have a variety of structural properties as is suited for the endovascular tool to be delivered. For example, guiding a fluid via guide tube **240** may not require the same structural properties as would be required from a piercing catheter or the like. Similarly, guide tube **240** can have a collapsible or flimsy configuration that expands as the endovascular tool passes through its lumen, if present. This collapsible configuration can reduce the profile of guide device **200** as traverses through the vasculature to the treatment site.

Guide tube **240** operatively couples or connects to expandable member **210** such that guide tube **240** outwardly or radially extends when expandable member **210** is its expanded position. In one embodiment, distal tip **241** is movable between a first position, in which the end of distal tip **241** is generally coaxial or generally parallel with expandable member **210** in its collapsed position, and a second position, in which distal tip **241** extends askew or in a generally orthogonal or radial direction, as expandable member **210** is expanded. Distal tip **241** of guide tube **240** may be operatively coupled to expandable member **210** coincident aperture **213**. In a different embodiment, distal tip **241** of the guide tube **240** may be coupled tangentially to expandable member **210**. However, the present disclosure includes any configuration that radially extends guide tube **240** when expandable member **210** is its expanded position such that an endovascular tool can pass through guide tube **240**.

In an exemplary embodiment, the distal tip **241** of guide tube **240** or a portion thereof comprises a radiopaque, echogenic, or magnetic material, or any other material capable of ex vivo detection. This material may be an integral part of tip **241**, a coating, or a separate marker connected thereto.

In various embodiments, guide device **200** may be configured to be a drug delivery device. For example, a drug may reside within expandable member **210** such that the drug is generally confined while expandable member **210** is in a collapsed position. Once expandable member **210** reaches the treatment site, expandable member **210** may expand to release the drug into the vasculature. In other embodiments, the drug may be injected into guide tube **240**, or an endovascular tool may comprise a drug delivery tool that can be delivered through guide tube **240** toward a desired treatment site. Such tools may be configured to penetrate a mass and deliver a drug directly into the mass.

In an embodiment, a method for using guide device **200** such as described herein may comprise the steps of deploying guide device **200** into a vessel and outwardly extending the expandable member **210** to an expanded position and thereby causing movement of distal tip **241** to its second position. Such expansion may be executed without substantially disrupting fluid flow through the vessel. Distal tip **241** in the second position may extend toward a treatment site on the vessel wall, thereby directing an endovascular tool passed through guide tube **240** toward the treatment site.

In an embodiment, expandable member **210** is outwardly extended by applying a compression force to expandable member **210**, such as through longitudinal displacement of second elongate member **230** relative to first elongate member **220**, thereby radially or outwardly extending distal tip **241**. Alternatively, expandable member **210** is outwardly extended by inflating an inflatable member.

A further embodiment comprises selectively positioning guide device **200** with the assistance of a detector, ex vivo, showing an in vivo position of the distal tip **241** or expandable member **210**. Then, an endovascular tool, such as that described in U.S. patent application Ser. No. 13/273,111 to Cully et al., may be advanced through the distal end of guide tube **240**. For example, FIG. **4** illustrates an endovascular tool **450** advanced through guide tube **440**. A further embodiment involves puncturing a selected site with endovascular tool **450**. A further embodiment involves injecting a contrast agent into guide tube **440** or an endovascular tool to verify a side branch has been fenestrated and/or cannulated or verify that the side branch is in fluid communication with the main vessel.

With reference to FIGS. **5**A and **5**B, various embodiments of the present disclosure comprise an endovascular target **510**A,B. Endovascular target **510**A,B is a temporary or permanent implant that serves as a target for an endovascular tool. Endovascular target **510**A,B facilitates the perfusion of fluid through a branch vessel **501**. An embodiment of endovascular target **510**A,B comprises an elongate member **513**A,B, with a lumen at least in the distal region of elongate member **513**A,B and at least one opening **512**A,B in the wall of elongate member **513**A,B accessing the lumen, and a distal anchor **511**A,B.

In an exemplary embodiment, distal anchor **511**A,B is configured to be positioned fixedly in branch vessel **501**. Distal anchor **511**A,B may be integral with elongate member **513**A,B or a separate structure attached thereto. Distal anchor **511**A,B may comprise a helix (e.g., as illustrated in FIG. **5**B), a ring, a perforated disc, an inflatable member (e.g., as illustrated in FIG. **5**A) or any structure configured to position fixedly in branch vessel **501**. Distal anchor **511**A,B may comprise detectable material such as a magnetic, radiopaque, echogenic, or fluorescent material, or any other material capable of ex vivo detection, such as with the use of electromagnetic radiation, fluoroscopy, an angioscope, or otherwise. In the case of the inflatable member, the inflation medium may be radiopaque. In exemplary embodiments, the diameter of distal anchor **511**A,B across the widest portion thereof when it is fixedly positioned is from about 1 mm to about 15 mm, from about 4 mm to about 7 mm, or from about 3 mm to about 6 mm. Distal anchor **511**A,B may be comprised of any number of materials including silicon, latex, polycarbonate, polysiloxane, polyurethane, polyvinyl chloride, polyethylene, nylon, PTFEs (e.g., ePTFEs), nitinol, or any biocompatible material, including combinations of the foregoing. In another embodiment, distal anchor **511**A,B comprises a coating of heparin or other anti-coagulant agent.

In embodiments, there may be any number, position, or configuration of opening **512**A,B in the wall of elongate member **513**A,B. Opening **512**A,B facilitates perfusion of the side branch vasculature. In an exemplary embodiment, the position of opening **512**A,B along elongate member **513**A,B is such that opening **512**A,B is located in main vessel **500** beyond the reach of a stent deployed in main vessel **500** when distal anchor **511**A,B is fixedly positioned in branch vessel **501**. This will allow a fluid such as blood to enter the lumen and facilitate perfusion of the side branch vasculature and downstream organs (e.g., kidneys). Opening **512**A,B may be configured such that blood readily passes through opening **512**A,B and into the lumen of elongate member **513**A,B, in a retrograde direction from that of the

main vessel if required. A flap may be utilized to facilitate one-way flow through opening **512** A,B.

In other embodiments, the wall of elongate member **513**A,B is not compromised. Stated another way, there is no opening for perfusion. The lumen extends to the hub of elongate member **513**A,B where the clinician may utilize it for perfusion of the side branch and its associated vasculature by injecting fluid, such as autologous blood or otherwise, with a syringe. In this embodiment, a clinician may see fit to modify by creating opening **512**A,B for retrograde perfusion by skiving the side of elongate member **513**A,B, for example, with a scalpel blade.

Another embodiment comprises the steps of deploying endovascular target **510**A,B as described herein into branch vessel **501** via main vessel **500** and fixedly positioning distal anchor **511**A,B in branch vessel **501**.

In an embodiment, a guide system may comprise an endovascular target and a guide device as described herein to facilitate the lateral and rotational positioning of the guide device. A further embodiment comprises a detector, an angioscope, or the like to facilitate the lateral and rotational positioning of guide device.

Another embodiment comprises the steps of deploying an endovascular target to a treatment area and positioning the endovascular target into branch vessel **501**. Further steps involve deploying a primary stent device in main vessel **500**, deploying a guide device as described herein to the grafted area, expanding the expandable member, and positioning the guide device relative to the endovascular target **510**A,B with the use of a detector, an angioscope, or the like. A further embodiment comprises deploying an endovascular tool through the guide tube to pierce the stent device proximate distal anchor **511**A,B. Other embodiments may comprise deploying a balloon device to the puncture site to expand the perforation and deploying a branch stent device to stent branch vessel **501**. Embodiments of the branch stent device may comprise a stent device, as that term is defined herein, gaskets, seals, flanges, self-expanding configurations, balloon-expanding configurations, or any combination of the foregoing.

Another embodiment comprises a guide device as described herein, configured to permit an angioscope to pass through the guide tube, a stent device comprising a transparent to translucent stent wall, and an angioscope. Once the stent device is deployed, the angioscope advances through the guide tube of the guide device. The guide device facilitates the lateral and rotational positioning. The angioscope permits the visual verification a branch vessel ostium through the transparent to translucent stent graft wall so that a fenestration tool or piercing guide tube may be deployed through the guide tube to fenestrate the stent graft at the branch vessel junction. A further embodiment may comprise deploying a balloon device to the pierced stent to expand the perforation and deploying a branch stenting device to stent the branch vessel.

In accordance with another exemplary embodiment and with reference to FIG. **6**H, a reverse cannulation system comprises a snare device **610** comprising an expandable member **615** as described herein, puncture guide device **620**, and a primary stent device **630**. The primary stent device **630** comprises a stent or a stent graft, both of which may be balloon expanding or self-expanding. An embodiment of a stent device comprises graft materials or fibers configured to prevent ripping or tearing upon puncturing or ballooning. In some embodiments, expandable member **615** may expand the primary stent device **630**. Once the stent is in position, the stent wall is fenestrated coincident the branch vessel from the exterior of the stent toward the interior with a puncture tool **621**. A puncture guide catheter **622** supports and guides a puncture tool **621** to the piercing site on the stent graft.

Puncture guide device **620** comprises a puncture guide catheter **622** having at least one lumen **623** with a perfusable anchor **624** at distal exterior of catheter **622** and a puncture tool **621** supportable by the puncture guide catheter **622**. In an exemplary embodiment, the puncture guide catheter **622** provides the required column strength via lumen **623** to the puncture tool **621** for piercing the primary stent device **630**. Puncture guide catheter may comprise a second lumen to allow for perfusion of blood to the kidney. Blood may be injected into second lumen as needed. The second lumen may be coated with heparin.

In accordance with an exemplary embodiment, puncture tool **621** comprises an elongate member and a tapered or sharp tip at a distal end. In other embodiments, puncture tool **621** may comprise a piercing catheter. In other embodiments, puncture tool **621** is energized with electromagnetic radiation, such as radio-frequency energy and the like, or mechanical energy.

An embodiment of perfusable anchor **624** can comprise at least one inflatable member connected to the distal exterior of catheter **622**. The inflatable member is of sufficient size to stabilize catheter **622** in the branch vessel. Other embodiments of perfusable anchor **624** comprise at least one ring connected to the distal exterior of catheter **622**, such that fluid passes through the ring and the ring assists in anchoring punch guide catheter **622**. Perfusable anchor **624** may comprise any number or variety of ringed geometric shapes connected to the distal exterior of catheter **622**. Perfusable anchor **624** may comprise an expandable, perfusable mechanical anchor, such as an expandable braid, in lieu of an inflatable member. Other embodiments of perfusable anchor **624** may comprise a perforated disc or the endovascular target as described herein.

In accordance with an embodiment, snare device **610** comprises an expandable member **615** as described herein. In an embodiment, first elongate member **612** and second elongate member **614** connect to an end opposite the other of expandable member **615** such that the longitudinal displacement of second elongate member **614** relative to first elongate member **612** expands and collapses expandable member **615**. Other embodiments of snare device **610** comprise the guide device as described herein. Use of expandable member **615** also allows for propping or bolstering the stent graft inner diameter in preparation for an in-situ fenestration. This added support may be helpful when puncturing strong stent graft material. Embodiments of snare device **610** may be configured to capture, hook, entangle, or the like a guidewire or puncture tool.

With reference to FIGS. **6**A-**6**M for purposes of illustration, another embodiment comprises the steps of accessing a side-branch through a lumbar access with a needle and/or lumbar stick (FIG. **6**A-**6**B); advancing a guide wire through the needle and gaining access through the branch vessel (e.g., renal artery) to the main vessel (e.g., aorta) (FIG. **6**C); removing the needle and/or lumbar stick; advancing a puncture guide device over the guide wire (FIG. **6**D); positioning the puncture guide device as described herein in the branch vessel near a junction with a main vessel (FIG. **6**D); withdrawing the guide wire from the main vessel (FIG. **6**E); advancing a primary stent device through the main vessel proximate the junction (FIG. **6**E); deploying the primary stent device (FIG. **6**F); advancing a snare device as described herein so that the expandable member is proxi-

mate the junction (FIG. **6**G); expanding the expandable member (FIG. **6**G); advancing a puncture tool through the puncture guide catheter to pierce the primary stent device and into the expandable member (FIG. **6**H); collapsing the expandable member and withdrawing the expandable member with the puncture tool in tow (FIG. **6**I). Because of these steps, an elongate member is threaded from a secondary access point into a branch vessel to the main vessel and out through a primary access point.

A further embodiment comprises the step of advancing a balloon catheter into the puncture site (FIG. **6**J); ballooning the punctured site to further open the puncture (FIG. **6**J); withdrawing the elongate member from the secondary access point into the branch vessel (FIG. **6**K); withdrawing the balloon catheter; advancing the secondary stent device through the punctured site (FIG. **6**L); and deploying the branch stent device (FIG. **6**M). Embodiments of the branch stent device may comprise gaskets, seals, flanges, self-expanding configurations, balloon-expanding configurations, or any combination of the foregoing.

Numerous characteristics and advantages have been set forth in the preceding description, including various alternatives together with details of the structure and function of the devices and/or methods. The disclosure is intended as illustrative only and as such is not intended to be exhaustive. For example, while the disclosure has been described primarily with reference to aortic applications, illustrative embodiments may be used in connection with other vessels having branched vessels extending therefrom. It will be evident to those skilled in the art that various modifications may be made, especially in matters of structure, materials, elements, components, shape, size and arrangement of parts including combinations within the principles of the disclosure, to the full extent indicated by the broad, general meaning of the terms in which the appended claims are expressed. To the extent that these various modifications do not depart from the spirit and scope of the appended claims, they are intended to be encompassed therein.

What is claimed:

1. A guide device deployable through a vessel comprising:

an expandable member including a plurality of slats, each of which is movable between a collapsed position and an outwardly extending, expanded position, at least one of the slats including an inner surface, an outer surface, and an aperture extending between and through the inner surface and the outer surface and the aperture being located on the slat that permits an endovascular tool to pass from a guide tube through the aperture;

the guide tube having a distal tip operatively coupled to the expandable member;

a first elongate member comprising a first lumen; and

a second elongate member comprising a second lumen, wherein the expandable member extends between a first end connected to the first elongate member and an opposite second end connected to the second elongate member, such that the expandable member expands outwardly in response to longitudinal displacement of the second elongate member relative to the first elongate member, wherein the longitudinal displacement of the second elongate member is configured to apply a compression or a tension force to the expandable member and is configured to result in a radial expansion of the expandable member.

2. The guide device of claim **1**, wherein the expandable member moves in response to selective actuation of the expandable member between the collapsed and expanded positions.

3. The guide device of claim **1**, wherein the guide tube is flexible and is configured to bend as the expandable member outwardly bends in response to corresponding longitudinal displacement of the second elongate member relative to the first elongate member.

4. The guide device of claim **1**, wherein the expandable member has a discontinuous structure to allow perfusion of fluid therethrough when in an expanded position.

5. The guide device of claim **1**, wherein the expandable member is configured to permit perfusion of fluid around the guide device when the expandable member is in the collapsed configuration and to permit perfusion between the plurality of slats of the expandable member when the expandable member is in the expanded positions.

6. The guide device of claim **1**, wherein the radial expansion of the expandable member is substantially radially symmetrical.

7. The guide device of claim **1**, wherein the expandable member comprises nitinol.

8. The guide device of claim **1**, wherein the expandable member is adjustable across a range of expanded position diameters.

9. The guide device of claim **1**, wherein the distal tip comprises a radiopaque material.

10. The guide device of claim **1**, wherein at least a portion of the first elongate member, the second elongate member, and the guide tube are coaxial along their lengths.

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